

**DECISIONS OF THE 26<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 06-01-2021**

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

S.No	Name of Establishment	Director/Proprietor/partners	Cold Chain (Yes/No)	Decision
1.	M/s Biocare Pharma B-175, Block H, North Nazimabad, Aziz Bhatti Road, Karachi.	Tariq Ahmed	No.	<b>Approved.</b>
2.	M/s Health Mark Scientific & Co, 302, Plot 99, Sharmeen Corner, Block 3, B.M.C.H.S., Bahadurabad, Karachi. <b>Godown:</b> Same as Above.	Muhammad Waleed	No	<b>Approved</b> for storage of room temperture medical devices.
3.	M/s Zam Zam Pharmaceutical, Suit No. 16, Ground Floor, 6-CL-10, Beaumont Plaza, Beaumont Road, Karachi.  <b>Godown Address:</b> Al-Madina Arcade, Shope No. 5, Clifton, Karachi.	Aamir Iqbal	Yes	<b>Approved.</b>
4.	M/s Nawan Laboratory (Pvt) Ltd. Plot No. 136-138, Sector 15, Korangi Industrial Area, Karachi.  <b>Godown:</b> Same as Above.	Mr. Ehsan Naseer Awan (CEO)	Yes	<b>Approved</b> for room temperature medical devices with cold chain facility.
5.	M/s Orient Traders International, Commercial-10,	Mr. Khalid Iqbal Mr. Shabana Musarrat	No.	<b>Approved.</b>

	<p>Block A, Kazimabad, Model Colony, Karachi.</p> <p><b>Godown-1:</b> CM Block-A, Kazimabad Model Colony, Karachi.</p> <p><b>Godown-2:</b> CM-18 Block-A, Kazimabad Model Colony, Karachi.</p>			
6.	<p>M/s Hakimsons (Impex) Pvt. Ltd, Hakimsons Building, 19 West Wharf Road, Karachi.</p> <p><b>Godown:</b> Same as Above.</p>	<p>Mr. Zulfiqar Ali Hakim (CEO)</p>	No.	<b>Approved.</b>
7.	<p>M/s Z.U International, 32-33 Muslim masjid, O/s Lahori Gate, Lahore.</p> <p><b>Godown:</b> Same as Above</p>	<p>Mr. Usman Bashir</p> <p>Mr. Zia Saeed</p>	No	<b>Approved.</b>
8.	<p>M/s MHK Enterprises, Jalal Heights, Flat No. 201, Plot No. 4, St.10D, &amp; 10P, Al-Hilal , C.H.S, Gulshan-e-Iqbal, Karachi.</p> <p><b>Godown Address:</b> N-118, Bloc-2, P.R.C.H.S., Karachi.</p>	<p>Mrs. Ghazala Rashid</p>	Yes.	<b>Approved</b> for room temperature medical devices with cold chain facility.
9.	<p>M/s Aqib Trading Company (Pvt) Ltd, Main G.T Road, Adamzai, AkoraKhattak, Nowshera.</p> <p><b>Godown Address:</b> 1<sup>st</sup> Floor, M/s Unisa Pharmaceutical Industries Ltd., Main G.T.oad, Adamzai, Akora Khattak,</p>	<p>Mr. Aqib Ismail</p> <p>Mrs. Samreen Aqib</p>	No.	<b>Approved</b> alongwith storage facility at 1 <sup>st</sup> Floor of M/s Unisa Pharmaceutical Industries Ltd., Main G.T.oad, Adamzai, Akora Khattak, District Noshera as the applicant is sister concern of M/s

	District Noshera.			Unisa Pharmaceutical Industries Ltd.
10.	M/s Al-Sharique Trading Company, Bungalow No. A/3, Block-C, Unit No. 5, Latifabad, Hyderabad.  <b>Godown:</b> Shop No. 4,5,6,7, My Mall apartments Unit No. 09, Latifabad, Hyderabad.	Mr.Sharique Khalid Farooqui	No	<b>Approved.</b>  <b>Qualification of Qualified Person is not as per MDR, 2017</b>
11.	M/s Tameer International, 112- Aziz Shaheed road, Cantt, Madina Town, Sialkot.	Shahida Parveen	No.	<b>Approved</b> for storage of non-cold chain medical devices.
12.	M/s Cenofex Enterprises, House No. 27, Street No. 02, New Lalazar Extension Rawalpindi.	Abdul Rehman  Muhammad Islam	No.	<b>Approved</b> for storage of room temperature medical devices.
13.	M.s Nolviva Pharmacon, Suit No. 312, 3 <sup>rd</sup> floor, Anum Blessing Block-7/8, K.C.H.S.U., Main Shahrah-e-Faisal, Karachi. <b>Godown:</b> Same as Above	Syed Naeem Jawed	No	<b>Approved</b> for storage of room temperature medical devices.
14.	M/s H.M Disposable, Suite No. 24-25, Mezzanine Floor, Kachi Gali No. 2, Marriot Road, Karachi.	Mr. Amir Malik	No	<b>Approved</b> for storage of room temperature medical devices.
15.	M/s Orbit Diagnostics, Apt No. 403, 4 <sup>th</sup> Floor, Plaza No. 55, Phase 4, Bahria Town, Islamabad.  <b>Godown:</b> Same as Above	Mr. Wajahat Qamar Butt  Mr. Usman Javaid	Yes	<b>Approved</b> for storage of room temperature medical devices and devices requiring cold chain.  DSL not Provided
16.	M/s AGBL Pakistan	Mr. Yasir Saleem	No.	<b>Approved</b> for

	(Pvt) Ltd., Office.508, 5th Floor, Parsa Topwer, Main Shahra-e-Faisal, Karachi.	Fady Al Assaly (CEO)		storage of room temperature and temperature sensitive medical devices.
17.	M/s Hakimi Medtech, Room No.4, Jason Centre, BC 8, Block-9, Clifton, Karachi.	Mr. Abbas Ali Sana Fawad	No.	<b>Approved</b> for storage of room temperature medical devices.
18.	M/s Silpha Labs (Pvt.) Ltd, 99/6, Gulshan-e-Mehrun Nisa, Ibrahim Hyderi, Korangi Creek, Karachi	Mr. Taimur Usman Mr. Faizan Usman	No.	<b>Approved</b> for storage of room temperature medical devices.  Dossier Missing
19.	M/s Diamond Star International, F-15 First Floor, Glass Tower, Adjacent PSO Head Office, Clifton, Karachi. <b>Godown Address:</b> F-08, First Floor, Glass Tower, Adjacent PSO Office, Clifton, Karachi.	Mr.Rohit Kumar	No.	<b>Approved</b> for storage of room temperature medical devices.
20.	M/s M.M. Brothers, Shop # 36, Madina Centre, Kutchi Gali No.1, Denso Hall, Karachi.	Mr. Mujeeb Ahmed	No	<b>Approved</b> for storage of room temperature medical devices.
21.	M/s Noori Enterprises, D-145, Block-5, F.B. Area, Karachi.	Lt. Col(R) Dr. Iftikhar Noori	No	<b>Approved</b> for storage of room temperature medical devices.
22.	M/s Reckitt Benckiser Pakistan Limited, Plot # 73, B, C & D, K-28 Phase-II, Trans Lyari Quarter, Hawksbay Road, Karachi.	Mr. Kashan Hasan	No.	<b>Rejected</b> due to the reason that the firm has hired the warehousing facility from connect logistics and have no dedicated place for storage of medical devices in that huge warehouse. Medical Devices are placed alongwith other consumable items.

				The firm has applied for DSL.
23.	M/s iEdge, Mezzanine Floor, Building No. 34-C, Lane No. 6, Ittehad Commercial Phase-VI, D.H.A., Karachi. <b>Godown:</b> 513-5 Sector 6/A, K.I.A. Mhran Town, Korangi, Karachi.	Mr. Muhammad Arbab Idrees  Tuba Ahsan	No.	<b>Approved</b> for storage of warm range temperature medical devices.
24.	M/s Humed Mfg Co., 78/6, Khaild Road Link Quaid-e-Azam Road, Sialkot Cantt.  <b>Godown Address:</b> Same as above.	Mr. Irfan Rafique Mr. Zain Irfan Ms. Mona Irfan Mr. Fraz Irfan	No	<b>Approved</b> for storage of room temperature medical devices subject to hiring of technical person.

## **2. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.**

### **2.1.**

M/s Anwer Khawaja Composite, Sialkot has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at **Sadra Badra, Daska Road, Sialkot.**

**Decision:** The Board after discussion decided to defer the grant of Establishment License to Manufacture Medical Devices since the firm does not have in-house QC testing facility.

### **2.2.**

M/s Zhong Cheng Producer Goods Trade (SMC-Private) Limited, Plot No.60-C, Street No.7, Sector I-10/3, Islamabad has informed that they are interested to install Manufacturing Unit for Medical Devices.

**Decision:** The MDB discussed the case and decided to reject the application of M/s Zhong Cheng Producer Goods Trade (SMC-Private) Limited, Plot No.60-C, Street No.7, Sector I-10/3, Islamabad for grant of establishment license to manufacture medical devices. The firm's was contacted telephonically and the firm's representative Mr. Binpent (Cell No.0312-

7038888) informed that the firm no more exists and their factory is closed. The Secretary, MDB directed to physically verify the status of the firm. Accordingly, the firm was visited and it was observed that the entry gates of the firm are locked. No person including any watchman was present at the premises nor any other activity was observed at the site during visit.

### **3. APPROVAL OF SITES FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.**

#### **3.1.**

M/s Medigar, Chak No.78 GB, Satiana Road, Faisalabad has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Chak No.78 GB, Satiana Road, Faisalabad.

**Decision:** The Board approved the site of M/s Medigar, Chak No.78 GB, Satiana Road, Faisalabad for establishment of manufacturing unit of medical devices.

#### **3.2.**

M/s Medicamp International, Office No. 1, 1<sup>st</sup> Floor, Raja Naseer Plaza, New Abadi, Rawalpindi has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Plot Khasra No.4340, New Bavli, Bhimber Road, P.O. Sokason, Tehsil & District, Bhimber, AJK.

**Decision:** The Board approved the site of M/s Medicamp International, Plot Khasra No.4340, New Bavli, Bhimber Road, P.O. Sokason, Tehsil & District, Bhimber, AJK for establishment of manufacturing unit of medical devices.

### **4. POST LICENSE VARIATIONS.**

#### **4.1.**

M/s Premier Agencies, Karachi has requested for approval of change of Establishment name and address and technical person in their ELI-00050 issued on 03-08-2018 as per detail given below:-

<b>Existing Name and Address of Establishment</b>	<b>Proposed Name and Address of Establishment</b>
M/s Premier Agencies, 60-Muslimabad,	M/s Premier Sales (Private) Limited, Head

Jamshed Quarters, M.A. Jinnah Road Extension, Karachi.	<b>Office:</b> Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi.
<b>Godown Address:</b> Plot No.D-3, D-4 & D-5, Sector 6-F, Mehran Town, Korangi, Karachi.	<b>Godown Address:</b> Plot No.D-3, D-4 & D-5, Sector 6-F, Mehran Town, Korangi, Karachi.
<b>Current Technical Person</b>	<b>Proposed Technical Person</b>
Ms. Sidra Perveen, Flat No.11, Block A/18, Rabia City, Gulistan-e-Johar, Karachi. CnIC # 42201-0517152-6	Syed Hassan Ali Jaffri, House # A-408, Block-12, Gulberg, F.B Area, Karachi. CNIC # 42101-8761390-5  B.Pharmacy

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

<b>Previous Name and Address of Establishment</b>	<b>New Approved Name and Address of Establishment</b>
M/s Premier Agencies, 60-Muslimabad, Jamshed Quarters, M.A. Jinnah Road Extension, Karachi.	M/s Premier Sales (Private) Limited, Head Office: Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi.
<b>Godown Address:</b> Plot No.D-3, D-4 & D-5, Sector 6-F, Mehran Town, Korangi, Karachi.	<b>Godown Address:</b> Plot No.D-3, D-4 & D-5, Sector 6-F, Mehran Town, Korangi, Karachi.
<b>Previous Technical Person</b>	<b>New Approved Technical Person</b>
Ms. Sidra Perveen, Flat No.11, Block A/18, Rabia City, Gulistan-e-Johar, Karachi. CnIC # 42201-0517152-6	Syed Hassan Ali Jaffri, House # A-408, Block-12, Gulberg, F.B Area, Karachi. CNIC # 42101-8761390-5  B.Pharmacy

#### 4.2.

M/s Zedco, Office No.203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi has requested for approval of change of qualified/technical person in their ELI-00347 issued on 27-02-2019 as per detail given below:-

<b>Existing Technical Person</b>	<b>Proposed Technical Person</b>
Ms. Asiya Amjad, House No.89, Alfalah Society Malir Halt, Malir, Karachi. CNIC # 42101-8842238-6	Mr. Maaz Uddin Ahmed Siddiqui, House No.B-53, Sector 18-A, KUEHS,, KDA Scheme 33 Gulzar-e-Hijri Gujroo, Malir Karachi.  CNIC # 42201-0270155-1  Pharm-D

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

<b>Previous Technical Person</b>	<b>New Approved Technical Person</b>
<b>Ms. Asiya Amjad, House No.89, Alfalah Society Malir Halt, Malir, Karachi. CNIC # 42101-8842238-6</b>	<b>Mr. Maaz Uddin Ahmed Siddiqui, House No.B-53, Sector 18-A, KUEHS,, KDA Scheme 33 Gulzar-e-Hijri Gujroo, Malir Karachi.  CNIC # 42201-0270155-1  Pharm-D</b>

#### **4.3.**

M/s Martin Dow Marker Specialities (Pvt) Limited, D-7, Parveen Building, Shaheed-e-Millat Road, Karachi has requested for approval of change of qualified/technical person in their ELI-00160 issued on 19-10-2018 as per detail given below:-

<b>Existing Technical Person for Karachi Warehouse</b>	<b>Proposed Technical Person for Karachi Warehouse</b>
<b>Ms. Tazeen karimi, House No.R-165, Sector 11-L, North Karachi, Karachi. CNIC # 42401-3068488-4  Warehouse Address: Plot 130, Sector -15, Korangi Industrial Area, Karachi.</b>	<b>Mr. Zalkifel Rao, Taj Court, Flat No.19, Manekji Street, Garden East, Karachi CNIC # 42000-6884546-9  Pharm-D  Warehouse Address: Plot 130, Sector -15, Korangi Industrial Area, Karachi.</b>

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

<b>Previous Technical Person for Karachi Warehouse</b>	<b>New Approved Technical Person for Karachi Warehouse</b>
<b>Ms. Tazeen karimi, House No.R-165, Sector 11-L, North Karachi, Karachi. CNIC # 42401-3068488-4  Warehouse Address: Plot 130, Sector -15, Korangi Industrial Area, Karachi.</b>	<b>Mr. Zalkifel Rao, Taj Court, Flat No.19, Manekji Street, Garden East, Karachi. CNIC # 42000-6884546-9  Pharm-D  Warehouse Address: Plot 130, Sector -15, Korangi Industrial Area, Karachi.</b>

#### **4.4.**

M/s Vantage Technologies, 251, Street 11-B, Phae-1, Ghouri Town, Islamabad Highway, Islamabad has requested for approval of change of qualified/technical person in their ELI-00219 issued on 18-10-2018 as per detail given below:-



<b>Existing Technical Person</b>	<b>Proposed Technical Person</b>
Mr. Muhammad Shahbaz Hussain, House No.195/6, Sharqi Colony, Janubi Block, Vehari.  CNIC # 36603-1450277-7	Sabayyel Hassan, Gujranwala Road, Street No.2, Mohallah Qazi Pura, Hafizabad.  CNIC # 34301-2823078-5  B.Sc (Hons) Allied Health Services (Medical Laboratory Technology).

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

<b>Previous Technical Person</b>	<b>New Approved Technical Person</b>
<b>Mr. Muhammad Shahbaz Hussain, House No.195/6, Sharqi Colony, Janubi Block, Vehari.</b>  <b>CNIC # 36603-1450277-7</b>	<b>Sabayyel Hassan, Gujranwala Road, Street No.2, Mohallah Qazi Pura, Hafizabad.</b>  <b>CNIC # 34301-2823078-5</b>  <b>B.Sc (Hons) Allied Health Services (Medical Laboratory Technology).</b>

#### **4.5.**

M/s Imtiaz Brothers, Suit No.7-B, 2<sup>nd</sup> Floor, Abrar Business Center, 25 main Wahdat Road, Lahore has requested for approval of change of qualified/technical person in their ELI-00133 issued on 17-10-2018 as per detail given below:-

<b>Existing Technical Person</b>	<b>Proposed Technical Person</b>
Ms. Nadia Tanveer, House No.539-B, Gulshan-e-Ravi, Lahore  CNIC # 35202-3583192-4	Ms. Syeda Urooj Shah, House No.12-E, Street No.4, Scheme No.01, Rachna Town, Ferozwala, District Sheikhpura. CNIC # 354011902301-2  Pharm-D

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

<b>Previous Technical Person</b>	<b>New Approved Technical Person</b>
<b>Ms. Nadia Tanveer, House No.539-B, Gulshan-e-Ravi, Lahore</b>  <b>CNIC # 35202-3583192-4</b>	<b>Ms. Syeda Urooj Shah, House No.12-E, Street No.4, Scheme No.01, Rachna Town, Ferozwala, District Sheikhpura.</b> <b>CNIC # 354011902301-2</b>  <b>Pharm-D</b>

#### 4.6.

M/s Grace Pharmaceutical, Karachi has requested for approval of change of Establishment address in their ELI-00254 issued on 19-10-2018 as per detail given below:-

<b>Existing Address</b>	<b>Proposed Address</b>
102, 1 <sup>st</sup> Floor, Block-9, Clifton, Karachi.	Office No.305, 5 <sup>th</sup> Floor, Plot No.42C/2, Lane-8 Bukhari Commercial DHA Phase-6, Karachi.

**Decision:** The Board acceded to the request of the firm /company and approved the change of establishment address as follows:-

<b>Previous Address of Establishment</b>	<b>New Approved Address of Establishment</b>
<b>102, 1<sup>st</sup> Floor, Block-9, Clifton, Karachi.</b>	<b>Office No.305, 5<sup>th</sup> Floor, Plot No.42C/2, Lane-8 Bukhari Commercial DHA Phase-6, Karachi.</b>

#### 4.7.

M/s Ontech Corporation, B-154, Block 13-D/2, Gulshan-e-Iqbal, Karachi has requested for approval of change of qualified /technical person in their ELI-00289 issued on 22-10-2018 as per detail given below: -

<b>Existing Technical Person</b>	<b>Proposed Technical Person</b>
Mr. Khurram Nawaz, Flat No. B-110, Sector 10-A, Mohalla Madina Blessing 1 <sup>st</sup> Floor, Gulshan-e-Iqbal, Karachi.  CNIC # 36302-3643588-9.	Mr. Zahoor Khan, House No.991, Block-21, Mohallah PIB Colony, Karachi. CNIC # 42401-7681128-9  B.Pharmacy

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

<b>Previous Technical Person</b>	<b>New Approved Technical Person</b>
<b>Mr. Khurram Nawaz, Flat No. B-110, Sector 10-A, Mohalla Madina Blessing 1<sup>st</sup> Floor, Gulshan-e-Iqbal, Karachi.</b>  <b>CNIC # 36302-3643588-9.</b>	<b>Mr. Zahoor Khan, House No.991, Block-21, Mohallah PIB Colony, Karachi.</b> <b>CNIC # 42401-7681128-9</b>  <b>B.Pharmacy</b>

#### 4.8.

M/s Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi has requested for approval of change of management (Directors/Partners) in their ELI-00019 issued on 03-08-2018, as per detail given below:-

Existing name (s) of Proprietors.	Proposed name (s) of Proprietors.
1. Mr. Anis Ahmed, B-140, Block N, North Nazimabad, Karachi. CNIC:42101-9990908-5.	1. Mr. Anis Ahmed, B-140, Block N, North Nazimabad, Karachi. CNIC:42101-9990908-5.
2. Mr. Munir Ahmed Shaikh, 96, Cairnill Road, Singapore, 229692: Passport No.488072827.	2. Mr. Munir Ahmed Shaikh, 96, Cairnill Road, Singapore, 229692: Passport No.488072827.
3. Mr. Kamran Y Mirza, House No.79, Street 4, Phase VI, Khayaban-e-Sehar, DHA, Karachi. CNIC: 42301-1126838-3.	3. Mst. Ayla Majid, House No.4, Zafar Akbar Road, Lalazar Colony, Rawlpindi. CNIC: 37405-2247801-4.
4. Mr. Shamim Ahmed Khan, House No.108, Street No.60, Sector I-8/3, Islamabad. CNIC:61101-7006861-7.	4. Mr. Mohsin Ali Nathani, House No.53, Street 18, Khayaban-e-Badbaan, Phase 5, DHA, Karachi. CNIC:42000-3154946-1.
5. Mr. Ehsan Ali Malik, 41A, South Central Avenue, Phase II, DHA, Karachi. CNIC:42301-7554100-1.	5. Mr. Ehsan Ali Malik, 41A, South Central Avenue, Phase II, DHA, Karachi. CNIC:42301-7554100-1.
6. Ms. Zehra Naqvi, 27-B, Circular Avenue, Phase I,DHA, Karachi. CNIC:42301-0639182-0.	6. Mr. Muhammad Anjum Latif Rana, 415-CC, Phase 4, DHA, Lahore Cantt. CNIC:35201-1678389-7.
7. Ms. Seema Khan, House No.SU-465, Askari V, Malir, Karachi. CNIC: 42501-2987789-0.	7. Ms. Seema Khan, House No.SU-465, Askari V, Malir, Karachi. CNIC: 42501-2987789-0.

**Decision: The Board acceded to the request of the firm /company and approved the change of management as follows:-**

Preious name (s) of Proprietors.	New Approved name (s) of Proprietors.
1. Mr. Anis Ahmed, B-140, Block N, North Nazimabad, Karachi. CNIC:42101-9990908-5.	1. Mr. Anis Ahmed, B-140, Block N, North Nazimabad, Karachi. CNIC:42101-9990908-5.
2. Mr. Munir Ahmed Shaikh, 96, Cairnill Road, Singapore, 229692: Passport No.488072827.	2. Mr. Munir Ahmed Shaikh, 96, Cairnill Road, Singapore, 229692: Passport No.488072827.
3. Mr. Kamran Y Mirza, House No.79, Street 4, Phase VI, Khayaban-e-Sehar, DHA, Karachi. CNIC: 42301-1126838-3.	3. Mst. Ayla Majid, House No.4, Zafar Akbar Road, Lalazar Colony, Rawlpindi. CNIC: 37405-2247801-4.
4. Mr. Shamim Ahmed Khan, House No.108, Street No.60, Sector I-8/3, Islamabad. CNIC:61101-7006861-7.	4. Mr. Mohsin Ali Nathani, House No.53, Street 18, Khayaban-e-Badbaan, Phase 5, DHA, Karachi. CNIC:42000-3154946-1.
5. Mr. Ehsan Ali Malik, 41A, South Central	

Avenue, Phase II, DHA, Karachi. CNIC:42301-7554100-1.	5. Mr. Ehsan Ali Malik, 41A, South Central Avenue, Phase II, DHA, Karachi. CNIC:42301-7554100-1.
6. Ms. Zehra Naqvi, 27-B, Circular Avenue, Phase I,DHA, Karachi. CNIC:42301-0639182-0.	6. Mr. Muhammad Anjum Latif Rana, 415-CC, Phase 4, DHA, lahore Cantt. CNIC:35201-1678389-7.
7. Ms. Seema Khan, House No.SU-465, Askari V, Malir, Karachi. CNIC: 42501-2987789-0.	7. Ms. Seema Khan, House No.SU-465, Askari V, Malir, Karachi. CNIC: 42501-2987789-0.

#### 4.9.

M/s IBL HealthCare Limited, Karachi has requested for approval of change of management (Directors/Partners) and office address in their ELI-00119 issued on 03-08-2018, as per detail given below:-

<b>Existing name (s) of Proprietors/Directors.</b>	<b>Proposed name (s) of Proprietors/Directors.</b>
<ol style="list-style-type: none"> <li>1. Mr. Rashid Abdullah, Houe No.5, Block 7/4, DMCHS, Tipu Sultan Road, Karachi. CNIC:42201-1132967-1.</li> <li>2. Mr. Adnan Asdar Ali, House No.B-40/1, Block 3, Clifton, Karachi. CNIC:42301-1091664-3.</li> <li>3. Mr. Syed Nadeem Ahmad, House No.86/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Ayaz Abdullah, House No.210, St. No.2, AFOHS, Falcon Complex, Main Shahrah-e-Faisal, Karachi. CNIC:42201-8726172-1.</li> <li>6. Ms. Shaista Khaliq, House No.54/1, St No.B-6<sup>th</sup>, Phase 5, DHA, Karachi. CNIC:42301-8797867-2.</li> </ol>	<ol style="list-style-type: none"> <li>1. Mufti Zia Ul Islam, Flat No.C-5, KDA Safari Terrace, FL-17, zand 26, Block 11, Gulshan-e-Iqbal, Karachi. CNIC:42000-0467228-3</li> <li>2. Mr. Rashid Abdullah, Houe No.6, Street No.9, Falcon Complex, AFOHS, Off Shaheed-e-Millat Road, Karachi. CNIC:42201-1132967-1.</li> <li>3. Mr. Shahid Abdullah, Houe No.5, Street No.9, Falcon Complex, Shaheed-e-Millat Road, Karachi. CNIC:42201-4240175-5.</li> <li>4. Mr. Syed Nadeem Ahmad, House No. B6/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>5. Mr. Zubair Razzak Palwala, House No.20, Street N, Phase 4, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>6. Mr. Shuja Malik, House No.33, Street No.20, Khayaban-e-Tanzeem, DHA-5, Karachi. CNIC:42301-1600531-9.</li> <li>7. Mst. Ameena Saiyid, House No.43-7, H Block-7, PECHS, Karachi. CNIC:42201-0421840-4.</li> </ol>
<b>Existing Address</b>	<b>Proposed Address</b>
1 <sup>st</sup> Floor, NICL Building, Abbasi Shaheed Rpad, Karachi.	Section A, 2 <sup>nd</sup> Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi.

**Decision: The Board acceded to the request of the firm /company and approved the change of address of establishment and management as follows:-**

<b>Previous Address of Establishment</b>	<b>New Approved Address of Establishment</b>
1 <sup>st</sup> Floor, NICL Building, Abbasi Shaheed Rpad, Karachi.	Section A, 2 <sup>nd</sup> Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi.
<b>Previous name (s) of Proprietors/Directors.</b>	<b>New Approved name (s) of Proprietors/Directors.</b>
<ol style="list-style-type: none"> <li>1. Mr. Rashid Abdullah, Houe No.5, Block 7/4, DMCHS, Tipu Sultan Road, Karachi. CNIC:42201-1132967-1.</li> <li>2. Mr. Adnan Asdar Ali, House No.B-40/1, Block 3, Clifton, Karachi. CNIC:42301-1091664-3.</li> <li>3. Mr. Syed Nadeem Ahmad, House No.86/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Ayaz Abdullah, House No.210, St. No.2, AFOHS, Falcon Complex, Main Shahrah-e-Faisal, Karachi. CNIC:42201-8726172-1.</li> <li>6. Ms. Shaista Khaliq, House No.54/1, St No.B-6<sup>th</sup>, Phase 5, DHA, Karachi. CNIC:42301-8797867-2.</li> </ol>	<ol style="list-style-type: none"> <li>1. Mufti Zia Ul Islam, Flat No.C-5, KDA Safari Terrace, FL-17, zand 26, Block 11, Gulshan-e-Iqbal, Karachi. CNIC:42000-0467228-3</li> <li>2. Mr. Rashid Abdullah, Houe No.6, Street No.9, Falcon Complex, AFOHS, Off Shaheed-e-Millat Road, Karachi. CNIC:42201-1132967-1.</li> <li>3. Mr. Shahid Abdullah, Houe No.5, Street No.9, Falcon Complex, Shaheed-e-Millat Road, Karachi. CNIC:42201-4240175-5.</li> <li>4. Mr. Syed Nadeem Ahmad, House No. B6/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>5. Mr. Zubair Razzak Palwala, House No.20, Street N, Phase 4, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>6. Mr. Shuja Malik, House No.33, Street No.20, Khayaban-e-Tanzeem, DHA-5, Karachi. CNIC:42301-1600531-9.</li> <li>7. Mst. Aameena Saiyid, House No.43-7, H Block-7, PECHS, Karachi. CNIC:42201-0421840-4.</li> </ol>

#### 4.10.

M/s Shirazi Trading Co. (Pvt) Ltd., Karachi has requested for approval of change of management (Directors/Partners) and office address in their ELI-00263 issued on 22-10-2018, as per detail given below:-

<b>Existing Address of the Establishment</b>	<b>Proposed Address of the Establishment</b>
8 <sup>th</sup> Floor, Adamjee House, I.I. Chundrigarh Road, Karachi.	No.114-CAI-Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, DHA, Karachi.
<b>Existing Name of Proprietors/Directors</b>	<b>Proposed Name of Proprietors/Directors</b>
Mr. Yusuf Hussain Shirazi,2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. 42301-3842441-9	Mr. Bashir Makki, House No.62/1, St. No.21, Khayaban-e-Baadban, Phase-5, DHA, Karachi. CNIC: 42301-0961322-3

Mr. Aamir Hussain Shirazai, House # 3, Zaman Park, Lahore. CNIC: 35202-3854859-7	Mr. Aamir Hussain Shirazai, House # 3, Zaman Park, Lahore. CNIC: 35202-3854859-7
Mr. Saqib Hussain Shirazi, House No.12, Street 5, Khayaban-e-Bukhari, Phase VI, DHA, Karachi. CNIC: 42000-0509678-5	Mr. Saqib Hussain Shirazi, House No.12, Street 5, Khayaban-e-Bukhari, Phase VI, DHA, Karachi. CNIC: 42000-0509678-5
Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0972346-1	Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0972346-1
Mr. Farooq Saleem, 111/2, Street 16 Khayaban-e-Muslim DHA 6, Karachi. CNIC:42301-3842441-9.	Mr. Farooq Saleem, 141/2, Street 16 Khayaban-e-Muslim Phase-6, DHA Karachi. CNIC:42301-3842441-9.
Mr. Khaleeq-ur-Rehman Khan Yousufi, House No.150/1, 35 <sup>th</sup> Street Khayaban-e-Muslim D.H.A VI, Karachi.	Mr. Iftikhar Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0948515-3.

**Decision: The Board acceded to the request of the firm /company and approved the change of address of establishment and management as follows:-**

<b>Previous Address of the Establishment</b>	<b>New Approved Address of the Establishment</b>
8 <sup>th</sup> Floor, Adamjee House, I.I. Chundrigarh Road, Karachi.	No.114-CAI-Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, DHA, Karachi.
Existing Name of Proprietors/Directors	Proposed Name of Proprietors/Directors
Mr. Yusuf Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. 42301-3842441-9	Mr. Bashir Makki, House No.62/1, St. No.21, Khayaban-e-Baadban, Phase-5, DHA, Karachi. CNIC: 42301-0961322-3
Mr. Aamir Hussain Shirazai, House # 3, Zaman Park, Lahore. CNIC: 35202-3854859-7	Mr. Aamir Hussain Shirazai, House # 3, Zaman Park, Lahore. CNIC: 35202-3854859-7
Mr. Saqib Hussain Shirazi, House No.12, Street 5, Khayaban-e-Bukhari, Phase VI, DHA, Karachi. CNIC: 42000-0509678-5	Mr. Saqib Hussain Shirazi, House No.12, Street 5, Khayaban-e-Bukhari, Phase VI, DHA, Karachi. CNIC: 42000-0509678-5
Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0972346-1	Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0972346-1
Mr. Farooq Saleem, 111/2, Street 16 Khayaban-e-Muslim DHA 6, Karachi. CNIC:42301-3842441-9.	Mr. Farooq Saleem, 141/2, Street 16 Khayaban-e-Muslim Phase-6, DHA Karachi. CNIC:42301-3842441-9.
Mr. Khaleeq-ur-Rehman Khan Yousufi, House No.150/1, 35 <sup>th</sup> Street Khayaban-e-Muslim D.H.A VI, Karachi.	Mr. Iftikhar Hussain Shirazi, 2-Khayaban-e-Ghazi Phase-V, DHA, Karachi. CNIC: 42301-0948515-3.



#### 4.11.

M/s Searle Company Limited, First Floor, N.I.C.L Building, Abbasi Shaheed Road, Karachi has requested for approval of change of management (Directors/Partners) and office address in their ELI-00057 issued on 03-08-2018, as per detail given below:-

<b>Existing name (s) of Proprietors/Directors.</b>	<b>Proposed name (s) of Proprietors/Directors.</b>
<ol style="list-style-type: none"> <li>1. Mr. Mobeen Alam, House No.32/2/2, Commercial lane Phawee 4, DHA, Karachi. CNIC:42301-6775803-3.</li> <li>2. Mr. Muhammad Sajid, House No.LS-158, St. No. Korangi, Sector 31-E, Lucknow Cooperative Housing Society, Karachi CNIC:42201-880829-1</li> <li>3. Mr. Tahir Ahmed, House No.6/6, 16 model colony, Karachi. CNIC:42201-0169711-5.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Moujood ul Hasan, House No.555, St.6 DOHS, Phase 1, Malir Cantt, Karachi. CNIC:35202-2434522-3.</li> <li>6. Dr. Imtiaz Haider, C-16, Gulshan-e-Iqbal, Block 4, Karachi East, Karachi: CNIC:42000-3720085-3.</li> </ol>	<ol style="list-style-type: none"> <li>1. Mr. Rashid Abdullah, House No.5, Block 7/4, DMCHS, Tipu Sultan Road, Karachi. CNIC:42201-1132967-1.</li> <li>2. Mr. Adnan Asdar Ali, House No.B-40/1, Block 3, Clifton, Karachi. CNIC:42301-1091664-3.</li> <li>3. Mr. Syed Nadeem Ahmad, House No.86/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Ayaz Abdullah, House No.210, St. No.2, AFOHS, Falcon Complex, Main Shahrah-e-Faisal, Karachi. CNIC:42201-8726172-1.</li> <li>6. Ms. Shaista Khaliq, House No.54/1, St No.B-6<sup>th</sup>, Phase 5, DHA, Karachi. CNIC:42301-8797867-2.</li> <li>7. Mr. Asad Abdullah, House No.2, Dehli Mercantile Society, Block 7/B, Karachi. CNIC:42201-8964822-9.</li> </ol>
<b>Existing Address</b>	<b>Proposed Address</b>
1 <sup>st</sup> Floor, NICL Building, Abbasi Shaheed Road, Karachi.	Section D, 2 <sup>nd</sup> Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi.

**Decision:** The Board acceded to the request of the firm /company and approved the change of address of establishment and management as follows:-

<b>Previous Address of Establishment</b>	<b>New Approved Address of Establishment</b>
1 <sup>st</sup> Floor, NICL Building, Abbasi Shaheed Road, Karachi.	Section D, 2 <sup>nd</sup> Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi.

Previous name (s) of Proprietors/Directors.	New Approved name (s) of Proprietors/Directors.
<ol style="list-style-type: none"> <li>1. Mr. Mobeen Alam, House No.32/2/2, Commercial lane Phaw 4, DHA, Karachi. CNIC:42301-6775803-3.</li> <li>2. Mr. Muhammad Sajid, House No.LS-158, St. No. Korangi, Sector 31-E, Lucknow Cooperative Housing Society, Karachi CNIC:42201-880829-1</li> <li>3. Mr. Tahir Ahmed, House No.6/6, 16 model colony, Karachi. CNIC:42201-0169711-5.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Moujood ul Hasan, House No.555, St.6 DOHS, Phase 1, Malir Cantt, Karachi. CNIC:35202-2434522-3.</li> <li>6. Dr. Imtiaz Haider, C-16, Gulshan-e-Iqbal, Block 4, Karachi East, Karachi: CNIC:42000-3720085-3.</li> </ol>	<ol style="list-style-type: none"> <li>1. Mr. Rashid Abdullah, House No.5, Block 7/4, DMCHS, Tipu Sultan Road, Karachi. CNIC:42201-1132967-1.</li> <li>2. Mr. Adnan Asdar Ali, House No.B-40/1, Block 3, Clifton, Karachi. CNIC:42301-1091664-3.</li> <li>3. Mr. Syed Nadeem Ahmad, House No.86/1, St. 24, Khayaban-e-Sehar, Phase 6, DHA, Karachi. CNIC:42301-0869989-9.</li> <li>4. Mr. Zubair Razzak Palwala, House No.27-B/11, Street No. Q, Phase 6, DHA, Karachi. CNIC:42201-5080780-3.</li> <li>5. Mr. Ayaz Abdullah, House No.210, St. No.2, AFOHS, Falcon Complex, Main Shahrah-e-Faisal, Karachi. CNIC:42201-8726172-1.</li> <li>6. Ms. Shaista Khaliq, House No.54/1, St No.B-6<sup>th</sup>, Phase 5, DHA, Karachi. CNIC:42301-8797867-2.</li> <li>7. Mr. Asad Abdullah, House No.2, Delhi Mercantile Society, Block 7/B, Karachi. CNIC:42201-8964822-9.</li> </ol>

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

### **5.1.**

The case of M/s Ghazali Brothers, Karachi for the below mentioned product was considered in the 12<sup>th</sup> MDB meeting held on 13-05-2019 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 Ghazali Brothers, 1 <sup>st</sup> Floor, Azzainab Court Campbell	<b>Manufacturer:</b> M/s Zhejiang Kindly Medical Devices Co., Ltd., No.758, 5 <sup>th</sup> Binhai	SpineLP Disposable Anaesthesia Needles  Class D	Anaesthesia (Spinal Needle)	<b>Approved</b> subject to foreign inspection abroad. The Board also



	Street, Karachi  (ELI-00240) Evaluator: Muhammad Ayub Naveed	Road Binhai Industrial Park, Longwan District 325025 Wenzhou, Zhejiang Province, P.R China.  (FSC China Valid Till 25-05-2019)  Fee Submitted Rs.50,000/-	Shelf Life: 5 Years  27G (0.4), 26G (0.45), 25G (0.5), 24G (0.55), 23G (0.6), 22G (0.7), 21G (0.8), 20G (0.9), 19G (1.1), 18G (1.2), 17G (1.4), 16G (1.6), 15G (1.8), 14G (2.1)		authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
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**Decision:** The Board approved the product of the firm on the basis of submitted Free Sale Certificate of Germany.

## 5.2.

The case of the M/s Ghazi Brothers, Karachi for the following products was considered in the 11<sup>th</sup> MDB meeting held on 01-02-2019 and was approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017. Now the firm has provided link to the website of Italy Ministry of Health where the below mentioned medical devices are listed and CE marked and has requested for issuance of registration certificates on the basis of above mentioned documents.

**Decision:** The Board approved the below mentioned products of the firm on the basis of submitted CE mark documents and availability on data base of Italy Ministry of Health.

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes /Class/Shelf Life	Brief Description	Decision
1.	M/s Ghazi Brothers, Ghazi House, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi  (ELI-00002)	<b>Legal Manufacturer/ Manufacturing Site:</b> M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date: 27-04-2017)	YVOIRE Contour  Class D  Shelf Life: 24 Months	Dermal Filler, Dermal Tissue Reconstructive Material, Microbe-Derived	<b>Approved.</b>
2.	-do-	<b>Legal Manufacturer/ Manufacturing Site:</b>	YVOIRE Classic Plus	Dermal Filler, Synthetic-Fluid	<b>Approved.</b>

		M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date: 27-04-2017)	Class D Shelf Life: 24 Months	Tissue Reconstructive Material, Anaesthetic	
3.	-do-	<b>Legal Manufacturer/ Manufacturing Site:</b> M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date: 27-04-2017)	YVOIRE Volume Plus  Class D Shelf Life: 24 Months	Dermal Filler, Synthetic-Fluid Tissue Reconstructive Material, Anaesthetic	<b>Approved.</b>

### 5.3.

The case of M/s Life-Tec, Islamabad for the below mentioned product was considered in the 15<sup>th</sup> MDB meeting held on 30-12-2019 and approved subject to provision of documents.

S.#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Brief description
1.	M/s Life-Tec Unit B, 1 <sup>st</sup> Floor, Block 20-D, G-8, Markaz, Islamabad.  ELI-00155	<b>Manufacturer:</b> M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China  FSC China valid till 3 <sup>rd</sup> July, 2020	Nigale Plasma Separator(Model: NGL XJC 2000)  Class: C  Service life: 5 years  Fee submitted: Rs 25,000/-	The Plasma Separator takes advantages of density difference of blood components of finish the process of centrifugation, separation, collection as well as returning rest components to blood donor. This equipment is indicated in collecting material plasma and preparing clinically fresh frozen plasma.

2.	M/s Life-Tec Unit B, 1 <sup>st</sup> Floor, Block 20-D, G-8, Markaz, Islamabad.  ELI-00155	<b>Manufacturer:</b> M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China  FSC China valid till 8-5- 2020	Nigale Disposable Blood Components Apheresis Set (Model: P-2000IA)  Class: C  Shelf Life: 4 years  Fee submitted: Rs 50,000/-	Intended to be used with blood component separating machine or blood cell separating machine for collection of blood platelet, collection of plasma, collection of red cell. Sterile, single- use
3.	M/s Life-Tec Unit B, 1 <sup>st</sup> Floor, Block 20-D, G-8, Markaz, Islamabad.  ELI-00155	<b>Manufacturer:</b> M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China  FSC China valid till 3 <sup>rd</sup> July, 2020	Nigale Blood Component Separator (NGL XCF-3000)  Class: C  Service life: 5 years  Fee submitted: Rs 50,000/-	Medical equipment that takes advantage of density difference of blood components to perform function of pheresis platelet or pheresis plasma through process of centrifugation, separation, collection as well as returning rest components to blood donor. This equipment is indicated in collecting and supplying blood sections or medical units which collect platelet and/or plasma

Now the firm has submitted the differential fee and valid free sale certificate of China and CE marked documents and requested to grant the registration of above mentioned products on the basis of CE marked documents.

Submitted for consideration of MDB.

**Decision:** The Board approved the above mentioned products of the firm on the basis of submitted CE mark documents.

## **6. REGISTRATION OF MEDICAL DEVICES FOR EXPORT.**

M/s Nisa SF Private Limited, Islamabad has submitted following applications for grant of registration of medical devices for export only under Medical Devices Rules, 2017:-

<b>Sr. No.</b>	<b>Name &amp; Address of Establishment</b>	<b>Name of Medical Devices With Size</b>	<b>Brief Description</b>
1	M/s Nisa SF Private Limited, 10-KM Muridke-Shaikhupura Road, Muridke District Punjab, Pakistan (ELM-0001)	<p>Venous Disposable Syringes</p> <p>Sizes:</p> <p>1ml with 26Gx½"(0.45mm x 13mm)</p> <p>1ml with 22G (0.7Mm x 30mm)</p> <p>2ml with 26G (0.7mm x 40mm)</p> <p>3ml with 24G X 1 " (0.55mm x 25mm)</p> <p>5ml with 23G X 1 " (0.6mm x 25mm)</p> <p>10ml with 21G X 1¼"(0.8mm x 32mm)</p> <p>20ml with 21G X 1½"(0.8mm x 38mm)</p> <p>Exemption for local manufacture upto 31<sup>st</sup> March, 2021 for 2ml, 2.5ml, 3ml and 5ml .</p> <p>Class B</p> <p>Shelf Life: 3 years</p> <p>Rs. 25,000/-</p>	Disposable Hypodermic Syringes
2	-do-	<p>Venous Disposable Infusion Set N.S.002</p> <p>Class B</p> <p>Shelf Life: 3 years</p> <p>Rs. 25,000/-</p>	Disposable Infusion Set

**Decision:** The MDB ratified the issuance of registration letters for above mentioned medical devices for export.

## **7. ACTION PLAN FOR INJECTION SAFETY TO BE IMPLEMENTED BY DRAP.**

**Decision:** The Board was briefed that Pakistan is facing multitude of public health crises due to rapidly rising burden of blood borne infections. The prevalence of Hepatitis C in our country is the highest in the World. It is estimated to be over 9% with a high incidence, which is resulting in addition of 240,000 new infections every year. Additionally, with 20,000 new HIV infections in 2017, Pakistan has the second fastest growing AIDS epidemic in the Asian region. These viruses are disproportionately affecting the most vulnerable and marginalized groups of our country.

The underlying cause of blood borne diseases in Pakistan is reuse of syringes. Currently injection rate per annum is between 8-10 injections. This is the highest number of per-capita injections anywhere in the World, which is worrying especially when we also have estimates that around 95% of these injections are completely unnecessary. The epidemiological investigations carried out for the 2019 HIV outbreak in Larkana suggest a strong association between unsafe injections (reuse of syringes and IV drip set) and transmission of injection. Prescription of unnecessary injection and injections given with reuse injection equipment is a common practice in Pakistan, especially in the private sector. These unsafe injections have also contributed significantly in increasing the burden of HCV in the country whereby Pakistan now has the highest number of HCV patient in the world. Other HIV outbreaks in parts of the country have also been attributed to unsafe injection practices of health care providers. More such outbreaks are expected as the underlying causes of bloodborne diseases like HBV, HCV and HIV/AIDS etc are the same. Ministry of National Health Services, Regulations & Coordination being committed to reduce the burden of bloodborne infections constituted National Task Force on Injection Safety to formulate strategy to address the menace of reuse/misuse of conventional disposable syringes.

Resultantly National Action Plan to address unsafe injection practices was launched on 17<sup>th</sup> December, 2019. It was recommended to Drug Regulatory Authority of Pakistan to take up the matter with Policy Board to completely stop import and manufacturing of 2ml, 2.5ml, 3ml & 5ml conventional disposable syringes and encourage the local production of the Auto-disable syringes.

The matter was placed before the Policy Board in its 32<sup>nd</sup> meeting and the Policy Board has endorsed the recommendations of National Action Task Force on Injection Safety.

To safeguard the public from the menace of reuse/misuse of conventional disposable syringes, the public interest requires that the import and manufacturing of 2ml, 2.5ml, 3ml and 5ml conventional disposable syringes be stopped with effect from 31<sup>st</sup> January, 2021 and 31<sup>st</sup> July, 2021 respectively.

**8. APPLICATIONS FOR GRANT OF ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICE.**

M/s UDL Distribution (Pvt) Limited, S-8/A, Translyari Quarters, SITE Near Gul Bai, in line of Meezan Bank, Head Office, Karachi has requested to grant of additional sizes of their following registered imported medical device as mentioned below:-

S.No	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0000439	Arrow Two Lumen Central Venous Catheters.	<p><b>Legal Manufacturer:</b></p> <p>M/s Arrow International, Inc (Subsidiary of Teleflex, Inc), 2400 Bernville Road Reading, PA 19605, USA.</p> <p>Manufacturing Site (s):</p> <p>1. M/s Arrow International de Chihuahua S.A de C.V, Ave, Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2,k Colonia Panamericana Chihuahua, Chihuahua CP31200, Mexico.</p>	CS-12702-E,CS-12802,CS-15802-E,CS-16702,CS-16702-E,CS-17702,CS-17702-E, CV-12702,CV-16702,CV-16702-E,CV-17702,CV-17702-E,ES-14702, CS-12402. CS-12402-J, CS-14402, CS-14502. CS-15402-E, CS-16402, ES-14402	CS-15802-E, CV-21712, ES-14702, CS-15402-E and CD-10802  As per Free Sale Certificate of HPRA, Ireland.

			2. M/s Arrow International C.R. a.s, Jamska 2359/47 Zdar Nad Sazavou, Vysocina 591 01, Czech Republic.		
2.	MDIR-0000437	Arrow Multi Lumen Central Venous Catheterization Set.	<b>-do-</b>	CS-12553-J,CS-12703-E,CS-12703,CS-12853-E,CS-14703,CS-14703-E,CS-15703,CS-15703-E,CS-15853-E,CS-1585 3,CS-16553-J,CV-12703,CV-12703-E,CV-14703,CV-14703-E,CV-15703,CV-15703-E, CS-15703-M, LS-15853, ML-00703, SS-14703, CS-15403 , CS-15553-E. CS-16553-E, CV-15553	CS-12123-F, CS-15123-F, CS-14553, BR-12853, BR-14853-EK, BR-15853, CV-12854, BR-12703 and BR-15703.

**Decision:** The Board acceded to the request of the firm /company and approved the additional sizes/codes of above mentioned medical device as mentioned below:-

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/Codes	New Approved Additional Sizes/ Codes.
1.	MDIR-0000439	Arrow Two Lumen Central Venous Catheters.	CS-12702-E,CS-12802,CS-15802-E,CS-16702,CS-16702-E,CS-17702,CS-17702-E, CV-12702,CV-16702,CV-16702-E,CV-17702,CV-17702-E,ES-14702,	CS-15802-E, CV-21712, ES-14702, CS-15402-E and CD-10802  As per Free Sale Certificate of HPRA, Ireland.

			CS-12402. CS-12402-J, CS-14402, CS-14502. CS-15402-E, CS-16402, ES-14402	
2.	MDIR-0000437	Arrow Multi Lumen Central Venous Catheterization Set.	CS-12553-J,CS-12703-E,CS-12703,CS-12853-E,CS-14703,CS-14703-E,CS-15703,CS-15703-E,CS-15853-E,CS-1585 3,CS-16553-J,CV-12703,CV-12703-E,CV-14703,CV-14703-E,CV-15703,CV-15703-E, CS-15703-M, LS-15853, ML-00703, SS-14703, CS-15403 , CS-15553-E. CS-16553-E, CV-15553	CS-12123-F, CS-15123-F, CS-14553, BR-12853, BR-14853-EK, BR-15853, CV-12854, BR-12703 and BR-15703.

## 9. ISSUANCE OF IMPORT PERMIT (FORM-10).

### Case No.1.

Mr. Munir Ahmed belonging from Skardu, Gilgit Baltistan has stated that he currently studying in Yangzhou University, Jiangsu Province, China as student of Master in Nutrition and Food Hygiene. Due to the current pandemic I am back to home and I was supposed to perform research work for my degree completion and opted to perform the research work over here in Pakistan and the selected topic is "**Study of Iron Nutrition in School Going Children of Skardu District**". For research study I need a machine (Body Analyzer) namely **Quantum Resonant Magnetic Analyzer**. From market survey there is no machine available in Pakistan and I had to import it from China.As I was in my village Skardu so I ordered machine stating my Nephew's name over it **Dr. Dawar** Shah as he is in Islamabad and its easy for the delivery purposes and other formalities.

He has requested for grant of permit to import **Quantam Resonant Magnetic Analyzer (Qty: 01)** from M/s Bai Dum Technology Co. Limited, China for the purpose of research to complete my degree.



Prompt the tested person grasp the test rod of the analyzer with the left or right hand. In the testing process, the tested person should feel relax, not speak and keep breathing balance. When the test is finished, the analyzer automatically judge, readout, analyze and give the report.

Quantum Resonance Magnetic Analyzer involves high-tech innovation projects of medicine, bio-informatics, electrical engineering and other sciences. using the quantum medicine as the theoretical basis, it applies the advanced electronic equipment to collect the weak magnetic field of human cells for scientific analysis, thereby analyzing and determining the tested person's health status and main problems and putting forward standard prevention recommendations. Quantum Resonance Magnetic Analyzer is individualized guide of health care consultation for full body and forward health science, and has the advantages of completeness, non-invasiveness, practicality, simplicity, fastness, economy, easy popularization etc. With the depth and development of scientific research, it will make a greater contribution for the cause of human health, having a broad development and application prospect.

**Decision: The MDB discussed the matter at length and decided to approve the issuance of import permit for Quantam Resonant Magnetic Analyzer (Qty: 01) to the applicant for research purpose.**

### **Case No.2.**

M/s Aprus Technologies Private Limited, Plot No.47/48 B, Industrial Estate, Jamrud Road, Peshawar has requested for grant of permit to import following medical devices manufactured by M/s Zhejiang Longterm Medical Technology Co., Ltd., China for the purpose of clinical investigation, examination, test or analysis (R&D) at **Aprus Technologies Private Limited, Plot No.47/48 B, Industrial Estate, Jamrud Road, Peshawar:-**

Sr. No.	Name of Medical Devices	Quantity
1.	Vacuum Sealing Drainage Dressing Kit	04 Pcs
2.	Wound Drainage Reservoir	02 Pcs
3.	Vacuum Sealing Dressing Kit	03 Pcs

Internal purpose of use of above mentioned medical devices is mentioned as under:-

1. **Vacuum Sealing Drainage Dressing Kit.** Vacuum Sealing Drainage (VSD) has been widely utilized in treatment of traumatic wounds for more than 17 years. A VSD device facilitates complete wound drainage and eliminates dead space, resulting in a decreased wound area, and enhanced formation of granulation tissue.

2. **Wound Drainage Reservoir.** Wound Drainage Reservoir prevents saturation of bandage material, decreases the risk for ascending infection, and can limit exposure of hospital staff or other patients to contaminated fluid. Active drains apply an artificial pressure gradient to pull fluid or gas from a wound or body cavity.
3. **Vacuum Sealing Drainage Dressing Kit.** Vacuum Sealing Drainage (VSD) has been widely utilized in treatment of traumatic wounds for more than 17 years. A VSD device facilitates complete wound drainage and eliminates dead space, resulting in a decreased wound area, and enhanced formation of granulation tissue.

**Decision:** The MDB discussed the matter at length and decided to approve the issuance of import permit for above mentioned medical devices to the applicant for the purpose of clinical investigation, examination, test or analysis (R&D) at Aprus Technologies Private Limited, Plot No.47/48 B, Industrial Estate, Jamrud Road, Peshawar.

#### **10. EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017**

##### **Case No.1.**

M/s Popular International (Pvt) Limited, 141, Justice Inamullah Road, Block 7 & 8, K.M.C.H.S, Near Hill Park, Karachi granted registration of following medical devices for import:-

<b>S.No</b>	<b>Reg.No.</b>	<b>Name of medical device(s)</b>
1.	MDIR-0000479	Permacol Collagen Paste
2.	MDIR-0000480	Parietex Optimized Composite Mesh.
3.	MDIR-0000481	Symbotex Composite Mesh
4.	MDIR-0000482	Permacol Surgical Implant
5.	MDIR-0000483	Progrip Laparoscopic Self-Fixating Mesh.
6.	MDIR-0000846	Vascufil Coated Monofilament Polybutester
7.	MDIR-0000847	PTFE Polymer Pledgets (Non-Absorbable Pre-Punched Pledgets)
8.	MDIR-0000848	V-LOC 90 Absorbable Wound Closure Device.
9.	MDIR-0000849	Ticron Coated Braided Polyester
10.	MDIR-0000850	NOVAFIL (Monofilament Polybutester)

11.	MDIR-0000851	CHROMIC GUT (Absorbable Suture)
12.	MDIR-0000852	SOFSILK (Wax Coated Braided Silk Silicone Coated Braided Silk).
13.	MDIR-0000853	V-LOC PBT (Non-Absorbable Wound Closure Device).
14.	MDIR-0000854	V-LOV 180 (Absorbable Wound Closure Device)
15.	MDIR-0000855	Flexon (Multifilament Temporary Cardiac Pacing Lead.
16.	MDIR-0000856	Maxon (Monofilament Absorbable Sutures)
17.	MDIR-0000857	Biosyn Monofilament Absorbable Suture.
18.	MDIR-0000858	Surgipro (Monofilament Polypropylene)
19.	MDIR-0000859	Caprosyn (Monofilament Absorbable Suture)
20.	MDIR-0000860	Surgiadic (uncoated Braided Polyester)
21.	MDIR-0000861	Polysorb (Braided Absorbable Suture)
22.	MDIR-0000862	Parietene Macroporous Mesh (Abdominal Hernia Surgical Mesh, Synthetic Polymer, Non-Bioabsorbable).
23.	MDIR-0000863	Progrip Self Gripping Polypropylene Mesh (Abdominal Hernia Surgical Mesh, Composite-Polymer).
24.	MDIR-0000864	Versatex Monofilament Mesh
25.	MDIR-0001200	Monosof Monofilament Nylon.
26.	MDIR-0001243	Parietene Lightweight Mesh Abdominal Hernia Surgical Mesh, Synthetic Polymer, Non-Bio Absorbable.
27.	MDIR-0001351	GIA Auto Suture Loading Unit with Stapler
28.	MDIR-0001352	EEA Auto Suture Circular Stampler
29.	MDIR-0001360	COVIDIEN Bone Wax (Haemostatic Bone Wax) Surgical Haemostatic Agents.

The firm has requested for grant of permission for printing establishment details such as MRP, Registration Number and Establishment License Number to comply with labeling Rules under MDR, 2017 in their licensed warehouse under supervision of their qualified pharmacist. The firm has deposited fee of Rs.10,000/- for the above-mentioned medical device.

They have further submitted that the BD Pen Needles are manufactured and packed for global sales in countries such as Europe, Japan, Canada and Australia etc. Since we consume very low quantity of these SKU's hence it is practically impossible for manufacturer to print Pakistan's local regulatory requirements such as Establishment License Number, Registration Number, Local Importers address and MRP on each pack specifically for Pakistan market. Hence it is impracticable for manufacturer to provide us the revised label as per MD Rules, 2017.

**Decision:** The MDB discussed the case and deferred for inspection of their establishment to assess whether the firm has the facility for printing of labeling at their warehouse.

### **Case No.2.**

M/s Premier Agencies, Karachi has requested for grant of permission for printing establishment details such as MRP, Registration Number and Establishment License Number to comply with labeling Rules under MDR, 2017 in their licensed warehouse under supervision of their qualified pharmacist for their following products:-

- i) BD Ultra Fine TM Pen Needle 32G x 4mm 320477.      MDIR-0000488
- ii) BD Micro Fine TM + Pen Needle 31G x 8mm 320471.      MDIR-0000487
- iii) BD Micro Fine TM + Pen Needle 31G x 5mm 320470      MDIR-0000489

**Decision:** The MDB discussed the case and deferred for inspection of their establishment to assess whether the firm has the facility for printing of labeling at their warehouse.

### **11. AMENDMENT IN NAME OF MANUFACTURER OF M. DIOR (MALE LATEX CONDOM) REGISTERED WITH DRAP ENLISTMENT/REGISTRATION NO. MDIR-0001294 DATED 13-02-2020.**

M/s M&M Pharma, 1<sup>st</sup> Floor, Javed Plaza, Opp Gate No.2, Pepsi Factory, Gurumangat Road, Gulberg II, Lahore has applied for the amendment in the name of legal manufacturer from M/s Suzhou Colour-way Enterprise Development Co. Ltd to M/s Suzhou Colour-Way New Material Co. Ltd., for its product M. Dior (Male Latex Condom) MDIR-0001294 dated 13-02-2020.

**Decision:** The MDB discussed the case and decided to approve the amendment in the name of manufacturer of above mentioned medical device from M/s Suzhou Colour-Way Enterprise Development Co., Ltd, 83-1 Changping Rd, Dongqiao area Xiangcheng District, Suzhou China to M/s Suzhou Colour-Way New Material Co. Ltd., 83-1 Changping Rd, Dongqiao area Xiangcheng District, Suzhou China.

## **12. EXTENSION IN SHELF LIFE.**

### **12.1.**

M/s Digital Imaging Systems, Lahore has requested for extension in shelf life of their already registered following imported medical devices: -

<b>Regn. No.</b>	<b>Name of Medical Device</b>	<b>Name of Manufacturer</b>	<b>Approved Shelf Life</b>	<b>Demanded Shelf Life</b>
MDIR-0000009	Xience Prime Everolimus Eluting Coronary Stent System	<b>Legal Manufacturer:</b> M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA  <b>Manufacturing Site:</b> M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland.  M/s Abbott Vascular 26531, YNEZ Road, Tenecula CA 92591, USA.  M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica  M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, US	02 Year	03 Years
MDIR-0000010	NC Trek RX Coronary Dilation Catheter	-do-	02 year	03 years
MDIR-0000011	Mini Trek RX Coronary Dilation Catheter	-do-	02 year	03 years
MDIR-0000012	Trek RX Coronary Dilation Catheter	-do-	02 year	03 years

**Decision:** The MDB discussed the case and decided to constituted a Committee comprising Dr. Ghazanfar Ali Khan, Additional Director (MDMC)/Secretary MDB and Dr. Muhammad Tahir Azia, Member MDB and refer the matter to the Committee for evaluation of application.

## 12.2.

M/s Islam & Sons, Near Ghee Mills Dargai, Malakand, KPK has requested for extension in shelf life of their already following registered medical devices import:-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
MDIR-0001893	RTMED Polyglycolic Acid Suture System	<b>Manufacturer:</b> M/s Shandong Haidike zMedical Products Co., Ltd, 88 Meters West of Tainfu Road, Dongcheng Office, Shan County Heze City Shandong Province, China.	03 Year	05 Years
MDIR-0001894	RTMED Silk Non-Absorbable Sutures	-do-	03 Year	05 Years
MDIR-0001895	RTMED Polypropylene Sutures with needle (non absorbable)	-do-	03 Year	05 Years

**Decision:** The MDB discussed the case and decided to constitute a Committee comprising Dr. Ghazanfar Ali Khan, Additional Director (MDMC)/Secretary MDB and Dr. Muhammad Tahir Azia, Member MDB and refer the matter to the Committee for evaluation of application.

## **13. 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
1.	M/s. Hospital Services & Sales, 13-C Annexe, Block 6, P.E.C.H.S, Karachi.  (Renewal)	<b>Legal Manufacturer:</b> M/s Wuxi Yushou Medical Appliances Co., Ltd No.115 Nongxinhe Road, Dongbeitang Town, Xishan District-214191, Wuxi City, Jiangsu Province, P.R. China.	<b>Yu Shou Auto Disable Syringes</b>  Class-B  Shelf Life: 5 years Sizes/ Codes: 0.05ml 0.1ml 0.5ml	Auto-disable syringes-destroyed after injection.

		FSC China valid till 27-12-2020	1ml 2ml 3ml	
		FSC Germany expired on 01-10-2013	5ml 10ml	
<b>Decision: The MDB approved the product subject to provision of shortcomings:</b> <b>MRP of the device</b> <b>Reference country FSC expired.</b> <b>QMS certificate expired.</b> <b>Labels missing</b>				
2.	AGP Limited, B-23-C, SITE, Karachi (ELI-00571)	<b>Legal Manufacturer:</b> M/s PT. Onject Indonesia Olympic Raya Kav. B9 Kawasan Industri Sentul Bogor 16810- Indonesia  FSC Indonesia valid till (15-06-2022) <b>WHO prequalified</b>	Oneject Auto Disable Syringe 1ml, 2ml, 3ml & 5ml  Class B  Shelf Life: 05 Years  Rs.25,000/-	Polypropylene syringe with latex free rubber gasket and stainless needle
<b>Decision: The MDB approved the product subject to provision of mentioned shortcomings:</b> Clarification needed as the applied device is not mentioned in FSC also verify the WHO prequalification status of the applied device. FSC of reference country as per Rule 67, duly attested by embassy of Pakistan. Real time shelf life studies of claimed shelf life. MRP of the device Essential principle of safety and performance/ Essential checklist as per EU Directive of 93/42/EEC. Labels of all applied sizes, approved in the country of origin.				
3.	M/s Zam Zam Pharmaceutical, Suit No.16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi (ELI-	<b>Legal Manufacturer:</b> M/s Jiangxi Sanxin Medtec Co., Ltd., No.999, Fushan Road, Xiaolan Economic Development Zone Nanchang Jiangxi, China  FSC China Valid Till (07-10-2021) <b>WHO prequalified</b>	Sterile Auto- Disable Syringe for fixed dose immunization 0.5ml, 0.1ml, 1ml, 2ml, 3ml & 5ml  Class B  Shelf Life: 05 Years	Sterile Auto-Disable Syringe for fixed dose immunization

			Rs.25,000/-		
<p><b>Decision: The MDB approved the product subject to provision of mentioned shortcomings:</b> Original and valid FSC in the country of origin clearly mentioning the product, duly attested.</p> <p>Labels of all applied sizes, approved in the country of origin.</p> <p>Notarized QMS &amp; FQA certificates, as the provided documents are without notarization</p>					
4.	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (Pvt) Ltd., D-2, 2nd Floor, Westland Trade Centre, Plot No.C-5, Block 7/8 KCHSU, Shaheed-e-Millat Road, Karachi (ELI-00374)	<p><b>Legal Manufacturer:</b> M/s Guangdong Haiou Medical Apparatus Co., Ltd., Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China</p> <p>FSC China Valid Till (07-10-2021)</p>	<p>Tie Shan Lan Needle Retractable Safety Syringe</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Rs.25,000/-</p>	<p>Needle Retractable Safety Syringe Single Use Sterile Needle Retractable Safety Syringe with needle</p>	The same manufacturer's syringes are already applied by hospital services, Lahore but with another brand name.
<p><b>Decision: The MDB discussed the matter at length and decided to reject the product at serial No. 4 as the same product from same manufacturer has already been registered in the name of M/s Hospital Services &amp; Sales, 13-C, Annex, Block PECHS, Karachi with brand name of Haiou Auto Disable Syringe with Needle.</b></p>					

#### 14. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi,	<p>Manufacturer: Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538</p> <p>(FSC USA valid till 06-11-2020)</p>	<p>Phenobarbital (Kit)</p> <p>Class C</p> <p>1.Phenobarbital Code: 5P07-21 Shelf life: 18 months</p> <p>Rs.50,000/-</p>	<p>Intended for the quantitative measurement of phenobarbital in human serum or plasma on the Architect c</p>	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p>



	Karachi (ELI-00019)		(Challan: 0580476)	Systems.	
2.	-do-	<p>Legal Manufacturer: B.R.A.H.M.S GmbH Neuendorfstrabe 25 D-16761 Henningsdorf Germany</p> <p>Manufacturing Site: Microgenics corporation 46500 Kato Road, Fremont California 94538 USA.</p> <p>(FSC Germany issued on 17-10- 2018)</p>	<p>Alinity c Digoxin Reagent Kit</p> <p>Class C</p> <p>Code: 08P3720</p> <p>Shelf Life: 12 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	Used for the quantitative in vitro measurement of digoxin in human serum or plasma on the Alinity c analyzer	<b>Approved</b>
3.	-do-	<p>Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p> <p>(FSC USFDA valid till 15-05- 2020)</p>	<p>Vysis ALK Break Apart FISH Probe Kit</p> <p>Class C</p> <p>i) ProbeChek ALK Negative Control Slides Code: 06N38-005 Shelf Life: 29 Months</p> <p>ii) ProbeChek ALK Positive Control Slides Code: 06N38-010 Shelf Life: 25 Months</p> <p>iii) Vysis ALK Break Apart FISH Probe Kit Code: 06N38-020 Shelf Life: 27 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	Qualitative test to detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with crizotinib.	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p>
4.	-do-	Manufacturer:	CEP 12 Spectrum	Intended to	<b>Approved</b>

		<p>M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p> <p>(FSC USFDA valid till 15-05- 2020)</p>	<p>Orange DNA Probe Kit with Control Slides</p> <p>Class C</p> <p>i) CEP 12 Spectrum Orange Code: 07J22-012 Shelf Life: 12 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>detect AT rich alpha satellite sequences in the centromere region of chromosome 12 in conjunction with routine diagnostic cytogenetic testing.</p>	<p>Before issuance of registration letter, firm shall provide valid FSC.</p>
5.	-do-	<p>Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p> <p>(FSC USFDA valid till 15-05- 2020)</p>	<p>Vysis CEP X Spectrum Orange/Y Spectrum Green DNA Probe Kit</p> <p>Class C</p> <p>i) Vysis CEP X Spectrum Orange/Y Spectrum Green Code: 07J20-050 Shelf Life: 12 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Intended to detect alpha satellite sequences in the centromere region of chromosome X and satellite III DNA at the Yq12 region of chromosome Y in conjunction with routine diagnostic cytogenetic testing.</p>	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p> <p>The firm shall submit separate application for Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Set.</p>
6.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSC USFDA Valid Till 13-09- 2019)</p>	<p>i-STAT EG6+ Cartridge (Kit)</p> <p>Class C</p> <p>i) i-STAT EG6+ Cartridge Code: 03P77-25 Shelf Life: 242 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Intended for use in the invitro quantification of carbon dioxide partial pressure, oxygen partial pressure, pH, sodium, potassium and red blood cell volume fraction in arterial, venous or</p>	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p>

				capillary whole blood.	
7.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSC USFDA Valid Till 13-09-2019)</p>	<p>i-STAT E3+ Cartridge (Kit)</p> <p>Class C</p> <p>Code: 03P82-25</p> <p>Shelf Life: 365 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	Intended for use in the invitro quantification of sodium, potassium and packed red blood cell volume fraction in arterial, venous or capillary whole blood.	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p>
8.	-do-	<p>Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p> <p>(FSC USFDA Valid Till 19-04-2019)</p>	<p>ViroSeq HIV-1 Genotyping System v2.0</p> <p>Class C</p> <p>Code: 4J94-93</p> <p>Shelf Life: 24 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	Intended for use in detecting HIV genomic mutations that confer resistance to specific types of antiretroviral drugs, as an aid in the monitoring and treating HIV infection	<p><b>Approved</b></p> <p>Before issuance of registration letter, firm shall provide valid FSC.</p>
9.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi (ELI-00091)	<p><b>Legal Manufacturer:</b> Covidien LLC, 15 Hampshire Street, Mansfield, MA USA 02048</p> <p><b>Manufacturing Site:</b> Covidien Building 911-67 Sabanetas Industrial Park Ponce, PR USA 00731</p> <p>FSC US FDA valid till 06-09-2019</p>	<p>TA™ Auto Suture™ Stapler with DST Series™ Technology</p> <p>Class C</p> <p>Codes: TA3035S TA3048S TA4535S TA4548S TA6035S TA6048S TA9035S TA9048S TA30V3S</p> <p>Shelf Life: 5 Years</p>	Has application in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue. May be used for transection and resection of pancreas. Sterile, single-use	<p><b>Approved</b></p> <p>The firm shall submit separate application for TA loading unit</p>

			Fee submitted: Rs. 50,000/-		
10.	M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037)	<p><b>Legal Manufacturer/ Manufacturing Site:</b> M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, UK</p> <p>(FSC Ireland Valid Till 11-09-2024)</p>	<p>IMMULITE 2000 Rubella IgG Assay Kit</p> <p>Class C</p> <p>IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB2 Shelf Life: 12 Months</p> <p>IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB6 Shelf Life: 12 months</p> <p>Fee submitted: Rs. 50,000/-</p>	For the quantitative measurement of IgG antibodies to rubella virus in human serum as an aid in the determination of immune status to rubella, particularly in women of child bearing age.	Approved
11.	<p>M/s Tech Zone, 764 Askari 9, Zarar Shaheed Road, Cantt, Lahore,</p> <p>Ware House: Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040</p>	<p><b>Legal Manufacturer &amp; Manufacturing Site:</b> Pikdare S.p. A Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO Italy.</p> <p>FSC Italy Issued on 24.05.2019</p>	<p>PIC Solution INSUMED [Insulin syringes with needle rigidly fixed (auto protect)]</p> <p>Class B</p> <p>Sizes: 0.3ml, 0.5ml, 1.0 ml Codes: As per FSC Italy dated 24-05-2020</p> <p>Shelf Life 5 years.</p> <p>Fee submitted: Rs. 25,000/-</p>	Sterile, single-use syringe for insulin administration	Approved
12.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas II,	<b>Manufacturer:</b> M/s. Intersurgical Limited, Crane House, Molly	Low Volume Manual Fill Humidification Chamber (with fill	It is used to humidify respiratory gases being	Approved

	Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi. ELI-00020	Millars Lane, Wokingham, Berkshire, United Kingdom.  FSC U.K issued on 01.03.2016	set and clamp) Ref No: 2330000 Class:B Shelf Life: 5 years  Fee submitted: Rs. 25,000/-	delivered to a patient. Single-use	
13.	-do-	<b>Manufacturer:</b> M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	30 mm UniFlow deluxe coaxial breathing system with 2L bag, integral monitoring line 1.6 mm (UniFlow Breathing System) Class B  Ref No: 2910000  Shelf Life: 3 years  Fee submitted: Rs. 25,000/-	It is used to deliver and remove anesthetic and respiratory gases from a patient via a system of tubing and connectors. Single-use	<b>Approved</b>
14.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore  (ELI: 00150)	Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany  Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany  FSC Germany Date of issue: 15-10-2019	Vista 120 (Patient Monitor)  Class-C  Ref: MS34008  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	Intended for multi-parameter patient monitoring of adult, pediatric and neonatal patients.	<b>Approved</b>  The firm shall apply for other models separately
15.	-do-	Manufacturer: Dragerwerk AG &Co. KGaA Moislinger Allee 53-55 D-23542 Lubeck, Germany  FSC Germany	Drager Savina 300 System (Intensive Care Ventilator)  Class: C  Ref: 8417800	Intended for the ventilation of adults and pediatric patients	<b>Approved</b>

		issued on 08-07-2020	Shelf Life: N/A  Fee submitted: Rs. 50,000/-		
16.	-do-	Manufacturer: Dragerwerk AG &Co. KGaA Moislinger Allee 53-55 D-23542 Lubeck, Germany  FSC Germany issued on 08-07-2020	Drager Oxylog VE300 (Emergency Care Ventilator)  Class: C  Ref: 5790200  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	It is a time-cycled, volume controlled and pressure-controlled emergency and transport ventilator for patients requiring mandatory or assisted ventilation with a tidal volume from 50 ml upward	<b>Approved</b>
17.	-do-	Manufacturer: Dragerwerk AG &Co. KGaA Moislinger Allee 53-55 D-23542 Lubeck, Germany  FSC Germany issued on 08-07-2020	Drager Oxylog 3000 Plus (Emergency Care Ventilator)  Class: C  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	A time-cycled, volume controlled and pressure-controlled emergency and transport ventilator for patients requiring mandatory or assisted ventilation with a tidal volume from 50 ml upwards.	<b>Approved</b>
18.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi  (ELI-00154)	Legal Manufacturer: Ethicon, LLC. 475 C Street, Los Frailes Industrial Park, Suite 401 Guaynabo, PR, USA 00969,.  Manufacturing Site: Ethicon Inc., Calle Durango No. 2751 Lote Bravo	PDS™ II (polydioxanone) suture (Synthetic, Monofilament, Absorbable Suture)  Class D  Shelf Life: 5 years  Codes: D6261 Z9108H Z9236T Z9394G	Intended for use in general soft tissue approximation, including use in pediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. Sterile, single-use	<b>Approved</b>

		<p>Ciudad Juarez, Chihuahua Mexico CP 32575.</p> <p>(FSC USFDA valid till 08-04- 2021)</p>	<p>Z359T W9095T W9096H W9100H W9101H W9102H W9108H W9115H W9116H W9124H W9125H W9133H W9233T W9234T W9236T W9237T W9394 W9865T</p> <p>(FSC of US FDA does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them)</p> <p>Fee submitted: Rs. 50,000/-</p>		
19.	<p>M/s. Horizon Group of Company, 603-Kamran Block, Allama Iqbal Town, Lahore.</p> <p>ELI-00140</p>	<p><b>Manufacturer:</b> M/s. Huaian Angel Medical Instruments Co., Ltd., 19 East Zhuhai Road, Huaian, Jiangsu 223001, China.</p> <p>Export Only Certificate from China valid till 01-02-2020</p>	<p><b>Stay Guard Sutures - Polydioxanone</b> (Polydioxanone Suture)</p> <p>(Codes not given)</p> <p>Class D</p> <p>Shelf Life: 36 months</p>	<p>PDO is indicated for use in general soft tissue approximation and / or ligation including use in plastic surgery; subcuticular; Pediatric;</p>	<p><b>Rejected</b>as thesutures of this manufacturer are already registered in the name of M/s Zenith International, Karachi</p>
20.	-do-	<p><b>Manufacturer:</b> M/s. Huaian Angel Medical Instruments Co., Ltd., 19 East Zhuhai Road, Huaian, Jiangsu 223001, China.</p> <p>Export Only Certificate from</p>	<p><b>Stay Guard Sutures - Polyglycolic Acid</b> (Polyglycolic Acid PGA)</p> <p>(Codes not given)</p> <p>Class D</p> <p>Shelf Life: 36 months</p>	<p>PGA is indicated for use in general soft tissue approximation and / or ligation including use in ophthalmic procedure;</p>	<p><b>Rejected</b>as thesutures of this manufacturer are already registered in the name of M/s Zenith International, Karachi</p>

		China valid till 01-02-2020		plastic surgery; subcuticular; Obstetrics; gynaecology; hepatic.	
21.	-do-	<b>Manufacturer:</b> M/s. Huaian Angel Medical Instruments Co., Ltd., 19 East Zhuhai Road, Huaian, Jiangsu 223001, China.  Export Only Certificate from China valid till 01-02-2020	<b>Stay Guard Sutures - Nylon</b> Polyamide (Nylon) suture  (Codes not given)  Class C  Shelf Life : 60 months	NYLON suture made of nylon refined, the surface smooth and no side effects, etc mainly used in ophthalmology and general surgery.	<b>Rejected</b> as the sutures of this manufacturer are already registered in the name of M/s Zenith International, Karachi
22.	-do-	<b>Manufacturer:</b> M/s. Huaian Angel Medical Instruments Co., Ltd., 19 East Zhuhai Road, Huaian, Jiangsu 223001, China.  Export Only Certificate from China valid till 01-02-2020	<b>Stay Guard Sutures- Polypropylene / Prolene</b> (Surgical polypropylene / prolene suture)  (Codes not given)  Class C  Shelf Life : Not mentioned in form.	The suture can be used for suturing many kinds of surgeries, such as skin wound, and the time to live in body is within 30 days.	<b>Rejected</b> as the sutures of this manufacturer are already registered in the name of M/s Zenith International, Karachi
23.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	Legal Manufacturer: M/s Fisher and Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand.  FSC New Zealand issuance 05-03-2020.	Bubble CPAP CPAP Unit  Class- B Shelf life:  Codes/ models: BC161-10: Bubble CPAP System BC151-10: Bubble CPAP System	A continuous positive airway pressure (CPAP) system is a medical device which is designed to keep a patient's airway open while providing respiratory ventilation so that the patient can breathe.	<b>Approved</b> subject to submission of CE marked document.



24.	M/s. Surgi World 303, Muhammad Plaza, College Road, Rawalpindi.  (ELI-00212)	<b>Legal Manufacturer:</b> Bard Access System, Inc. 605 North 5600 West Salt Lake City, Utah (UT) USA.  <b>Manufacturing Site:</b> M/s Bard Reynosa S.A DE. C.V Blvd Montebello No.1 Parque Industrial Colonial Reynosa, Tamaulipas, Mexico  FSC USA Valid till, November, 18,2020	HEMOSTAR Long Term Hemodialysis Catheter (Long term Hemodialysis Catheter)  Class D  Shelf Life 2 years  Codes/ models: 5833150-5833270 5833310-5833350 5833690-5833730 5834420	The HEMOSTAR® Long Term Hemodialysis Catheter are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy.	<b>Approved.</b>
25.	-do-	<b>Legal Manufacturer:</b> Bard Peripheral Vascular, Inc. 1625 W 3 <sup>rd</sup> st Tempe, AZ USA 85281  (FSC US FDA valid till 28-11-2020)	<b>IMPRA ePTFE vascular Grafts</b> Vascular Grafts  Class C  Shelf Life: 5 Years  Codes As Per FSC	IMPRA ePTFE vascular Grafts are constructed of expanded polytetrafluoro ethylene. They are indicated for use as vascular prostheses.	<b>Approved.</b>
26.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi  (ELI-00030)	<b>Legal Manufacturer:</b> Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, CH <b>Manufacturing site:</b> <b>HTL-STREFA S.A. ul. Lotnicza 21h, 99-100 Leczyca, Poland.</b>	Microlet® Next Lancing Device  Class B Shelf Life: 05 Years  Sizes & Codes as Per FSC	It is used for obtaining capillary blood samples from the fingertip. Capillary samples can be obtained from the palm as well.	<b>Approved.</b>

		(FSC Switzerland valid 17-10-2022)			
27.	-do-	<b>Legal Manufacturer:</b>  Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, CH. <b>Manufacturing site:</b> <b>HTL-STREFA S.A. ul. Adamowek 7, 95-035 Ozorkow, Poland.</b>  (FSC Switzerland valid 17-10-2022)	Microlet® Lancets  Class B Shelf Life: 05 Years  Sizes & Codes as Per FSC	It is single use lancets intended for capillary blood sampling. The needle of the lancet is sterile and covered with a plastic cap, which is removed prior to the use of the lancet.	<b>Approved.</b>
28.	M/s KASBN International, 422-A-1 GULBERG III NEAR GHALIB MARKET LAHORE  (ELI-00434)	<b>Legal Manufacturer:</b> NOUVAG AG LOCATED at St. Gallerstrasse 23-25, 9403, Goldach, Switzerland.  FSC: Switzerland Valid till 30.07.2022	<b>(NOUVAG) SUCTION PUMP</b>  Class B  Shelf Life: N/A  Codes/ models: 4227-115-4227-230-	The Nouvag suction pumps is used for suction of fluids and secretions.	<b>Approved.</b>
29.	M/s. Ahmad Medix Pvt (Ltd) 129/6 Quaid-e-Aza, Industrial Estte, Township, Lahore.  ELI-00380	<b>Legal manufacturer</b> ROOSIN MEDICAL CO Ltd, 8 Yuandong Road Gaogang, China.  FSC China validity 25-09-2021.	Burn Care (Relieve burn Gel Spray)  Class C  Shelf Life: 05 years  Codes/ models: Spray/ 59bottles/118bottle/25 bottle	Burn Care gel is used for the first aid treatment of burns and scalds quickly absorbing and releasing heat through evaporation of water so as to cool the skin, keep the wound moist and prevent from being dry and	<b>Deferred</b> forprovision of reference country Free Sale Certificate or inspection of manufacturer abroad.

				cracked.	
30.	M/s S.Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078)	<b>Manufacturer:</b> HemoCue AB Box 1204 SE-262 23 Angelholm Sweden, Kuvettgatan 1, 262 71 Angelholm  (FSC Sweden validity 25-05-2022)	HemoCue WBC Diff System (Analyzer & Microcuvettes)  Class B  Shelf Life: 13 Months  Article No. 123512, 113503	The HemoCue WBC Diff System is designed for quantitative determination of white blood cells in capillary and venous whole blood. The System can be used in pediatric and adult patients.	<b>Approved.</b>  The firm shall submit FQA certificate before issuance of registration letter.
31.	-do-	<b>Manufacturer:</b> Osang Healthcare Co., Ltd. 132, Anyangcheondong- ro, Dongan-gu, Anyang-si, and Gyeonggi-do Korea.  (FSC Korea issue on 21-05-2019)	HemoCue HbA1c 501 System  Glycated Haemoglobin (HbA1c) analyser IVD  Class B  Shelf Life: Not mentioned  HemoCue HbA1c 501 System  Gyeongin 09-105 Hemoglobin analyser	The Hemocue® HbA1c 501 system is used for the quantitative measurement of percent concentration of hemoglobin A1c (HbA1c ) in whole blood capillary and venous. The measurement of hemoglobin A1c concentration is recommended for monitoring the average blood glucose levels, for long-term care of people with diabetes.	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad.
32.	M/s Mana & Co., Office No. 401, 4 <sup>th</sup> floor, Masood chamber Shahrah e Liaqat, Karachi., Karachi (ELI-00280) [2820]	<b>Legal Manufacturer:</b> M/s Xiamen Ants- bro Technology Co., Ltd, 4F, 5th Building, Technology Business Establishing Center, No.289 Wengjiao Road,	Medisign Digital Thermometer  Class B  Shelf Life: 04 Years  Rs. 25,000/-  Models: TM-2011	Digital Thermometer	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad.

		Haicang District, Xiamen City, Fujian Province China  FSC China Valid Till (07-04--2022)	TM-3002		
33.	-do-	<b>Legal Manufacturer:</b> M/s Xiamen Ants- bro Technology Co., Ltd, 4F, 5th Building, Technology Business Establishing Center, No.289 Wengjiao Road, Haicang District, Xiamen City, Fujian Province China  FSC China Valid Till (07-04--2022)	Medisign Infrared Forehead Thermometer  Class B  Shelf Life: 04 Years  Models: HA-610 HA-620 HA-630 HA-640 HA-650  Rs.25,000/-	Infrared Forehead Thermometer	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad.
34.	M/s Asto Life Sciences Pvt Ltd, 44/1, K Block Model Town Lahore  ELI-00103	<b>Legal Manufacturer</b> Becton, Medical (S) Pte Ltd 30 Tuas Avenue 2, Singapore 539461 Singapore  FSC: Singapore issuance 20-11-2018	BD <sup>TM</sup> precision glide needles 18G-27G (BD Hypodermic Needles 18G to 27 G)  Class-B  Shelf life: 5 years  Codes/ sizes as per FSC.	BD Hypodermic Needles are single use, sterile sharp bevel-edged, hollow tubular metal device intended to be used in conjunction with syringes, secondary medication sets or phlebotomy equipment's to prepare and administer fluids/ medications/ drugs to a patient and/or withdrawn from the patient.	<b>Deferred for</b> provision of reference country Free Sale Certificate or inspection of manufacturer abroad.
35.	M/s. AL-Walli Care Concepts	<b>Legal Manufacture:</b>	<b>CONIC ONE</b> (PTCA BALLOON	CONIC ONE PTCA is	<b>Approved.</b>

<p>86-Allama Iqbal Road Garhi Shahu Lahore</p> <p>ELI-00386</p>	<p>CONIC VASCULAR TECHNOLOGY, S.A. Via Carlo Maderno, 23 CH-6901 Lugano, Switzerland</p> <p><b>Manufacturing Site:</b></p> <p>CONIC VASCULAR ESPANA, S.L. C/ENTRERRIOS, N 9 bajo 15220 Ames, Span.</p> <p>FSC: Switzerland</p> <p>Valid till: 11.06.2022</p>	<p>CATHETER) C1-150/125X15 C1-150/125X20</p> <p>C1-150/125X15 C1-150/125X20 C1-225/175X30 C1-200/175X15 C1-250/200X30 C1-225/200X15 C1-275/225X30 C1-250/225X15 C1-300/250X30 C1-275/250X15 C1-325/275X30 C1-300/275X15 C1-350/300X30 C1-325/300X15 C1-400/350X30 C1-350/325X15 C1-450/400X30 C1-400/375X15 C1-225/175X35 C1-200/175X20 C1-250/200X35 C1-225/200X20 C1-275/225X35 C1-250/225X20 C1-300/250X35 C1-275/250X20 C1-325/275X35 C1-300/275X20 C1-350/300X35 C1-325/300X20 C1-400/350X35 C1-350/325X20 C1-450/400X35 C1-400/375X20 C1-225/175X40 C1-225/175X25 C1-250/200X40 C1-250/200X25 C1-275/225X40 C1-275/225X25 C1-300/250X40 C1-300/250X25 C1-325/275X40 C1-325/275X25 C1-350/300X40 C1-350/300X25 C1-400/350X40 C1-400/350X25</p>	<p>indicated in patients with significant coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery and who meet one of the following selection criteria. Atherosclerotic coronary artery disease that is accessible with a dilation catheter. ii. Corona ry artery disease of the native coronary arteries and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery and who have recurrence of symptoms and (a) progression of disease or (b) stenosis and closure of the grafts</p>	
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			C1-450/400X40 C1-450/400X25 C1-200/150x25 C1-200/150X25  Class D  Shelf Life:2.5 Years		
36.	-do-	<u>Legal Manufacture:</u> CONIC VASCULAR TECHNOLOGY, S.A. Via Carlo Maderno, 23, CH- 6901 Lugano, Switzerland  Manufacturing Site:  CONIC VASCULAR ESPANA, S.L. C/ENTRERRIOS, N 9 bajo 15220 Ames, Span.  FSC: SwitzerLand Validity: 11.06.2022	CLEVER PTCA BALLOON CATHETER  Size Variants:  CV-200-10 CV-200-15 CV-200-25 CV-225-10 CV-225-15 CV-225-20 CV-225-25 CV-225-30 CV-200-35 CV-225-40 CV-250-15 CV-250-20 CV-250-25 CV-250-30 CV-250-35 CV-250-40 CV-275-10 CV-275-15 CV-275-20 CV-275-25 CV-275-30 CV-275-35 CV-275-40 CV-300-10 CV-300-15 CV-300-20 CV-300-25 CV-300-30 CV-300-35 CV-300-40 CV-325-10 CV-325-15 CV-325-20 CV-325-25 CV-325-30 CV-325-35 CV-325-40 CV-350-10 CV-350-15	Clever PTCA is indicated in patients with significant coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery and who meet one of the following selection criteria. Atherosclerotic coronary artery disease that is accessible with a dilation catheter. ii.  Corona ry artery disease of the native coronary arteries and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery and who have recurrence of symptoms and (a) progression of disease or (b) stenosis and closure of the	Approved.

			CV-350-20 CV-350-25 CV-350-30 CV-350-35 CV-350-40 CV-400-10 CV-400-15 CV-400-20 CV-400-25 CV-400-30 CV-400-35 CV-400-40 CV-450-20 CV-450-25 CV-450-30 CV-450-35 CV-450-40  Class D  Shelf Life: 2.5 years	grafts	
37.	M/s Sultansons, 133 Kutchi Gali No.1, Marriott Road, Karachi (ELI-00051) [2726]	<b>Legal Manufacturer:</b> M/s Wellex Company, Cairo-Ismailia Desert Road, Ismailia Public Free Zone, 41639 Ismailia City, Egypt Limited Company.  FSC Egypt Issuance Date 18-02-2020 <b>Reference country FSC Germany issuance 11-11-2019</b>	Wellex (IV Cannula with Port)  Class B  Shelf Life: 05 Years  Rs.25,000/-  Codes/ sizes as per FSC	IV cannula with port is used for infusion of I.V solution suitable for administration via peripheral vein.	<b>Approved.</b>
38.	M/s. LENS House 3 <sup>rd</sup> Floor, Musarat Plaza, AInak Market Shah ALam, Market Lahore. ELI-00397	Legal Manufacturer: Polytouch Co.Ltd 129-4 Hyeopseok 2 gil Namcheonmyeon, Gyeongsan si, Gyeongsangbuk-do Republic of Korea.  FSC Korea Issuance 03-02-	Soft contact lense daily wear  Class C  Shelf Life 5 years.  Models: NK New comfort Comfort 60	Lens	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad.

		2020			
<b>39.</b>	M/s. Chemical House 6-C Sikandar Malhi Road, Canal park, Gulberg II, Lahore.  ELI-00156	<b>Legal Manufacturer</b> 3 Boulevard Raymond Poincare, 92430 Maranes-la, Conquette, France  FSC- France  Date of issue 15.3.2018	Monolisa HCV Ag-AB Ultra V2 Assay (cat # <b>72561, 72562</b> )  (EIA Microplate Format)  Code: 2734000  Class D  Shelf Life: 18 months	Monolisa HCV Ag-AB Ultra V2 Assay Is a qualitative enzyme immunoassay for detection of infection by hepatitis C virus based on the detection of anti HCV antibodies and capsid antigen in serum and human plasma.	<b>Approved.</b>  The firm shall submit the updated LOA before issuance of registration letter.
<b>40.</b>	M/s. Novatek Pakistan. P-20 Ist Floor, Chenab Market, Susan Road, Madina Town, Faisalabad.  (ELI-00454)	<b>Legal Manufacturer:</b> M/s. Akida Holdings LLC, 13500 Sutton Park Dr. South, Suite 501, Jacksonville, FL, 32224, USA.  FSC State of Florida Issued on 16.04.2019	<b>Airocide</b>  Airocide Model No. GCS-25 Air Purification System GCS-50 Air Purification System GCS-100 Air Purification System  Class B Service Life: 7-10 years	Airocide (Air Purification System) is true filter less air purifier. It uses a NASA developed catalyst to safely remove all organic material from the air.	<b>Deferred</b> for provision of following documents:  Certificate to Foreign Government issued by US FDA for the applied product. Clarification if the device is CE marked under the EU medical device directive and provision of CE marking documents. ISO 13485 issued for USA
<b>41.</b>	M/s Balta Impex, SH.40, Namco Centre, Cambell Street, Karachi. (ELI-00170)	<b>Legal Manufacturer:</b> Haiyan Kangyuan Medical Instrument Co., Ltd Songpodong Rd., Shengdang Town, Haiyan Zhejiang Province, China.  (FSC China Valid till 08-07-2019)	Golden + Silicon Foley Catheter  Class B  Shelf Life: 5 Years Sizes: 6Fr, 8 Fr, 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28Fr  Rs.25,000/-	A Foley catheter is a thin, sterile tube inserted into the bladder to drain urine.	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad and submission of valid FSC.



42.	-do-	<b>Legal Manufacturer:</b> Haiyan Kangyuan Medical Instrument Co., Ltd Songpodong Rd., Shengdang Town, Haiyan Zhejiang Province, China.  (FSC China Valid till 08-07-2019)	Golden + Endotracheal tubes  Class B  Shelf Life: 5 Years Sizes: ID2.0, ID2.5, ID3.0, ID3.5, ID4.0, ID4.5, ID5.0, ID5.5, ID6.0, ID6.5, ID7.0, ID7.5, ID8.0, ID8.5, ID9.0, ID9.5, ID10.0 Rs.25,000/-	A <b>tracheal tube</b> is a catheter that is inserted into the tracheal for the primary purpose of establishing and maintaining a patent airway and to ensure the adequate exchange of oxygen and carbon dioxide.	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad and submission of valid FSC.
43.	M/s. Renacon Pharma Ltd. House No,3 Street No 1, 18 Km, Ferozepur Road, Mujahid Colony Lahore.  ELI-00177	<b>Manufacturer</b> M/s. Jiangxi Sanxin Medtec Co., Ltd, No.999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, 330200, P.R. China.  FSC China Valid till 18-10-2020	<b>Renav AV Fistula Needle</b> (Fistula Needle for Hemodialysis)  Class C  Shelf Life: 02 years  Models & sizes: A type, B type 1.8mm (15G), 1.6mm (16G), 1.4mm (17G), 1.2mm (18G)	Fistula Needle for Hemodialysis.	<b>Deferred</b> for provision of reference country Free Sale Certificate or inspection of manufacturer abroad and submission of valid FSC.
44.	M/s Global Health Care, Midway Commercial Plaza No. 20, BackSide of prism Arcade 2, Phase 7 Bahria Town, Rawalpindi.  (ELI-00086)	<b>Legal Manufacturer:</b>  Boditech Med Inc. 43, Geodudanji 1-gil, Dongnaemyeon, Chuncheon-si, Gangwon-do, Korea.  (FSC Korea Issuance 19-10-2018) FSC Belgium issuance 20-11-2019	<b>Ichroma™ Ferritin</b>  Test for Ferritin  Class B  Shelf Life: 20 Months Control stability studies of kit and control  Codes: CFPC-32	Ichroma™ Ferritin fluorescence Immunoassay (FIA) for quantitative determination of Ferritin in human Serum/plasma. It is useful as an aid in quantifies human ferritin. For in vitro diagnostic use only.	<b>Approved</b>
45.	-do-	<b>Legal Manufacturer:</b>  Maxter Malaysia Super Max Gloves Manufacturing	King Malaysia  (Sterile Powdered Latex Surgical Gloves)	Latex surgical gloves is made from 100% natural rubber and sterile by gamma	<b>Deferred</b> for provision of reference country Free Sale Certificate

		SDN, BHD lot 38, Industrial Park, Bukit Rehman Putra 40160 Sungai Bulob Selangor Darul Ehsan Malaysia.  FSC Malaysia (original)  Valid till: 20-06-2020	Class B  Shelf Life 5 years.	radiation then treated with USP grade modified corn starch which is to facilitate the user in donning the glove and to prevent from sticking each other. It is used to protect the wearer against contamination of infectious material, it is used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures.	or inspection of manufacturer abroad.
46.	M/s Hashir Surgical Services office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar. Office No.05, 2 <sup>nd</sup> Floor, Syed's Tower, University Road, Peshawar. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar  ELI: 00075	<b>Legal Manufacturer:</b> M/s Revital Healthcare (EPZ) limited, LR No.5025/1239 Msumarini-Mombasa-Malindi Rd P.O BOX 80713-80100 Mombasa-Kenya.  FSC: Kenya Date of issue: 31 <sup>st</sup> December, 2019 WHO Prequalified	<b>REVITAL Re-use prevention syringes</b>  Shelf Life: 12 months  Sizes: 2ml, 5ml, 10ml  Class B	Provides access to a vein of a patient in order to sample blood, inject medication.	<b>Approved</b> subject to sample inspection.  Manufacturer issue same manufacture of A.J Mirza Pharma (Pvt) Ltd., Karachi
47.	M/s Krestacorp, 76-C, 3 <sup>rd</sup> Floor, Suit No.2, Khayaban-e-	<b>Legal Manufacturer/ Manufacturing Site:</b> M/s Karex	Feel Flavoured condoms  Natural rubber latex Male Condoms	Natural Rubber Latex Condoms is a non-Sterile, Single use device made of	<b>Approved</b> subject to change of Brand name.

	Jami, Street No.9, DHA Phase 07, Karachi	Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor DarulTakzim, Malaysia  (FSC Malaysia Valid Till 13-02-2021) FSC reference country MHRA issuance 30-01- 2019	Class C Shelf Life: 5 Years  Sizes & Codes: P53S Rs.50,000	natural rubber latex, lubricated with silicone oil. It is Packed in a rolled-up form in an individual heretically sealed square foil sachet comprises of polyester/ aluminum/ Polyethylene/ LDDPE. Foiled condoms are packaged in cardboard outer boxes. It is used for contraception and prevention of sexually transmitted disease.	
48.	M/s Zenith International Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. <b>ELI: 00090.</b> <b>127-(K)-MD</b>	<b>Manufacturer:</b> M/s Zheijiang Bangli Medical Products Co., Ltd., No. 118 Yuegui South Road City, West New District 321300 Yongkang City, Zhejiang Province, China	<b>PERFECT PLAST,</b> Disposable Plaster. Shelf Life: 60 months. Class-A.	Disposable Plaster	<b>Approved</b> subject to provision of valid ISO 13485/ GMP certificate &FSC of country of origin.
49.	<b>-do-</b>	<b>Manufacturer:</b> M/s Hospital & Hemocare Medical Devices Co., Ltd., No. 188 East of Jingwu Road, West Side, Ye Ya Science and Technology Park, Jianhu, Jiangsu, China	<b>PERFECT</b> Disposable Heparin Cap. Shelf Life: 60 months. Class-B.	Disposable Heparin Cap	<b>Approved</b> subject to inspection of manufacturer abroad and provision of valid ISO 13485/ GMP certificate & FSC of country of origin.
50.	M/s. Freesia Enterprises Address: First Floor,104	<b>Legal</b> <b>Manufacturer:</b> M/s. <b>PLASTI-</b> <b>MED</b>	<b>UMBILICAL CORD</b> <b>CLAMP.</b>  Class: B	The umbilical cord clamp allows the passage of	<b>Approved</b> subject to inspection of manufacturer

	Dawn Plaza, Bank Road, saddar, Rawalpindi	Deri OSB Mahallesi Yn Sanayi Cad. No: 13 Tuzla/Istanbul Turkey. FSC Turkey Date of issue.3 <sup>rd</sup> April,2017.	Shelf Life: 02- 05years.	oxygenated blood from the placenta to the fetus through the abdomen.	abroad and submission of original fee slip endorsed by Directorate Budget & Account, DRAP.
51.	M/s deKhon, 11-C Old FCC, Ferozpure Road, Gulberg- III, Lahore. <b>ELI-000317.</b>	<b>Legal Manufacturer</b>  TRB Chemedica Ag Otto- Lilienthal-Ring 26, D-85622 Feldkirchen/Munch en, Germany  Production Facility (VISmed Gel)  Pharma Stulln GmbH WerksstraBe 3 92551 Stulln, Germany  Pharmaster Z I ErsteinKrafft 67150 Erstein France.  FSC: Germany  Date of Issue: 14.06.1993	<b>i. Vismed ® Gel Multi.</b> (Sodium Hyaluronate 0.3% GEL) <b>ii. Vismed Multi ®.</b> (Sodium Hyaluronate 0.18%) Class: C. Shelf Life: 36 months.	Sodium Hyaluronate 0.3% GEL	<b>Approved the product; Vismed ® Gel Multi.</b> (Sodium Hyaluronate 0.3% Gel) subject to provision of application form is not signed &stamped and undertaking given by firm is not on stamp paper.
52.	-do-	<b>Legal Manufacturer</b>  FB Vision s.r.l Via Piceno Aprutina 47, 63100 Ascoli Piceno  Production Facility Name of Firm OMISan Farmaceutici S.R.l Address: VIA Galileo Galilei, 00012 Guidonia	<b>OZODROP ® Ophthalmic solution.</b> {Hypromellose & 10% Liposomes}. Class: C. Shelf Life: 24-Monhs.	OZODROP is a protective , lubricating, moisturising and soothing ophthalmic solution for the ocular surface, based on hypromellose, liposomes and ozonated vegetable oil useful for: Facilitating reparative	<b>Approved;</b> subject to provision of application form is not signed & stamped, stability studies and undertaking given by firm is not on stamp paper.

		Montecelio (Rome) Italy FSC: Italy Date of Issue: 27.04.2020		processess after surgical or traumatic stress the treatment of symptoms related to inflammation als of infectious origin	
53.	<b>M/s. Safe Health Pakistan Bizcon,</b> Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, <b><u>Karachi.</u></b>	<b>Legal Manufacturer:</b> M/s Guangdong Intmed Medical Appliance Co., Ltd., South Shunhe Road Europe Industry Park, Shunde, District, Foshan City, Guangdong, China  FSC China Valid Till (30-06-2019) FSC Ireland Valid Till (23-07-2019)	<b>Disposable Syringes with Needle</b> (30ml & 50ml)  <b>Class-B</b>	<b>Disposable Syringes with Needle</b>	<b>Deferred;</b> firm asked to provide the original fee slip/ or importer's copy; • Provide, justifiable stability study data, technical details of EPSP, labels (approved in country of origin), QA Certificate and original and valid FSC of country of origin. In case of failure to comply, the case will be considered for rejection by MDB.
54.	<b>-do-</b>	<b>Legal Manufacturer:</b> M/s Guangdong Intmed Medical Appliance Co., Ltd., South Shunhe Road Europe Industry Park, Shunde, District, Foshan City, Guangdong, China  FSC China Valid Till (30-06-2019) FSC Ireland Valid	<b>Disposable Syringes with Needle</b> (1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml)  <b>Class-B.</b>	<b>Disposable Syringes with Needle</b>	<b>Deferred;</b> firm asked to provide the original fee slip/ or importer's copy; • Provide, justifiable stability study data, technical details of EPSP, labels (approved in country of origin), QA Certificate and original and valid FSC of

		Till (23-07-2019)			country of origin. In case of failure to comply, the case will be considered for rejection by MDB.
55.	-do-	<b>Legal Manufacturer:</b> M/s Bao Health Medical Instrument Co., Ltd., 2nd Floor of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang, Zhejiang, P.R. China  FSC China Valid Till (19-07-2020)	<b>Bao Helath</b> (Ostomy Care Bag)  Class B	It is used to collect output from a stoma	<b>Deferred;</b> firm asked to provide the original fee slip/ or importer's copy; <ul style="list-style-type: none"> <li>• Provide, justifiable stability study data, technical details of EPSP, labels (approved in country of origin), QA Certificate and original and valid FSC of country of origin.</li> </ul> In case of failure to comply, the case will be considered for rejection by MDB.
56.	M/s.Abbott Labs. (Pakistan) Ltd.Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, <u>Karachi.</u>	Legal Manufacturer: M/s Abbott Laboratories, 1921 Hurd Dr Irving, TX 75038, USA  FSC USFDA Valid Till (03-03-2021)	<b>TRANSFERRIN</b> (IVD Cluster for Anemia Diagnosis.)  Shelf- life: 13months.  Class B	IVD Cluster for Anemia Diagnosis	<b>Approved;</b> subject to provision of ISO-13485, MRP, original agency agreement and FSC.
57.	-do-	Legal Manufacturer: M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA.	<b>ALINITY c ICT Serum Calibrator.</b>  Shelf- life: 15months.  Class B	ICT Serum Calibrator	<b>Approved the product;</b> <b>ALINITY c ICT Serum Calibrator.</b> subject to provision of ISO-13485,

		FSC      USFDA Valid Till (08-02-2020)			MRP, original agency agreement and FSC.
58.	-do-	<b>Legal Manufacturer:</b> Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany.  (FSC      Germany Issuance    14-10- 2016)	<b>ARCHITECT Anti-CCP</b> IVD-Reagent Kit.  Shelf Life: 18 Months.  Class B	The Architect Anti-CCP assay is a chemiluminescent microparticle immunoassay (CMIA) for semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citullinated peptide CCP in human serum or plasma on the architect system iSystem.	<b>Deferred;</b> for submission of ISO-13485/ GMP certificate, MRP, technical information of QC. And current status of the product in Germany or FSC of any SRA country.
59.	-do-	<b>Legal Manufacturer:</b> Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany.  (FSC      Germany Issuance    14-10- 2016)	<b>ALINITY Anti-CCP</b> IVD-Reagent Kit.  Shelf Life: 13-Months.  Class B	The alinity Anti-CCP assay is a chemiluminescent microparticle immunoassay (CMIA) for semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citullinated peptide CCP in human serum or plasma on the architect system iSystem.	<b>Approved;</b> subject to provision of ISO-13485, MRP, original agency agreement and FSC.
60.	-do-	Legal Manufacturer:	<b>ALINITY c Hemoglobin A1c IVD</b> Reagent                      Kit.	<b>ALINITY c Hemoglobin A1c IVD</b>	<b>Approved the product;</b> subject to

		Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany.  (FSC Germany issue 19-07-2018)	Shelf Life: 15 Months.  Class B	Reagent Kit	provision of ISO-13485 and MRP.
61.	-do-	Legal Manufacturer: Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany.  (FSC Germany Issuance 12-06-2019)	<b>ALINITY i C-Peptide &amp; Insulin</b> IVD-Reagent Kit. Shelf- life: 11-months  Class B	<b>ALINITY i C-Peptide &amp; Insulin</b> IVD-Reagent Kit	<b>Approved the product; ALINITY I C-Peptide.</b>
62.	-do-	Legal Manufacturer: Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany.  (FSC Germany issue 26-03-2019)	<b>ARCHITECT c Bilirubin</b> (Total, Direct & In-Direct). IVD Reagent Kit. Shelf Life: 18 Months.  Class B	<b>ARCHITECT c Bilirubin</b> (Total, Direct & In-Direct). IVD Reagent Kit	<b>Approved;</b> subject to provision of stability study duly signed and stamped and MRP.
63.	-do-	Legal Manufacturer: M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.  FSC USFDA Valid Till (21-01-2021)	<b>ARC c4000</b> Processing Module, Integrated. (IVD-Machine)  Class A	Processing Module, Integrated	<b>Approved</b> subject to provision of service life protocols and studies.
64.	-do-	Legal Manufacturer: M/s Sekisui Medical Co. Ltd. 1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan.  FSC UK Issuance Date	<b>CP3000</b> Main Unit with; <b>CTS CP3000</b> System A & <b>PC 230V</b> Cuvettes (5000). (IVD-Machine)  Class A	<b>CP3000</b> Main Unit with; <b>CTS CP3000</b> System A & <b>PC 230V</b> Cuvettes (5000). (IVD-Machine)	<b>Deferred;</b> For provision of following shortcomings/clarifications: Provide service life protocols & studies, ISO-13485/ GMP certificate,



		(11-05-2017)			original agency agreement & FSC; Provide the application on Form-7A with all coded particulars and differential fee as per decision of MDB.
65.	-do-	<p>Legal Manufacturer: M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.</p> <p>FSC USFDA Valid Till (24-02-2021)</p>	<p><b>i-STAT-1</b> Wireless Analyzer. (Model No.300W)</p> <p>Class B</p>	Wireless Analyzer.	<p><b>Deferred;</b> For provision of following shortcomings/clarifications: Provide service life protocols &amp; studies, clarification of storage &amp; working conditions; Provide the application on Form-7A with all coded particulars and differential fee as per decision of MDB.</p>
66.	-do-	<p>Legal Manufacturer: M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.</p> <p>FSC USFDA Valid Till (24-02-2021)</p>	<p><b>i-STAT ALINITY</b> Instrument. (Model No. AN-500)</p> <p>Class B</p>	<b>i-STAT ALINITY</b> Instrument	<p><b>Deferred;</b> For provision of following shortcomings/clarifications: Provide service life protocols &amp; studies, clarification of storage &amp; working conditions; Provide the application on Form-7A with all coded particulars and differential fee as per decision of MDB.</p>

67.	-do-	Legal Manufacturer: M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.  FSC USFDA Valid Till (26-12-2020)	<b>CELL-DYN RUBY</b> Analyzer. (IVD-Machine)  Class A	Analyzer. (IVD- Machine)	<b>Approved subject to</b> provision of application on Form-7A with all coded particulars and differential fee as per decision of MDB.
68.	-do-	Legal Manufacturer: M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.  FSC USFDA Valid Till (09-10-2020)	<b>ARCHITECT</b> 2000SR Analyzer. (IVD-Machine)  Class B	Analyzer. (IVD-Machine)	<b>Approved subject to</b> provision of service life protocols & studies, original and Valid FSC and application on Form-7A with all coded particulars and differential fee as per decision of MDB.
69.	<u>M/s Mubarak Vision,</u> 32-A Usman Centre, Shah ALam Market, Lahore. <u>ELI-00045.</u>	Legal Manufacturer  MD-TECH Srl Via De Gasperi 35, 00165 Rome Italy  FSC FDA U.S. FOOD & DRUG FSC: Italy Date of issue: 23- 01-2020	<b>I-STREAM IOL</b> (ISP60GL). Class: C.	Aspheric Hydrophobic Non-Preloaded Foldable IOL/ Aspheric Hydrophobic Preloaded Foldable IOL	<b>Deferred</b> for submission of priority to consider in this application and all remainder devices shall be applied separately.
70.	-do-	Legal Manufacturer  IRIDEX 1212 Terra Bella Avenue, Mountain View, CA 94043- 1824 USA  FSC USA	<b>IRIDEX</b> Ophthalmic lasers + Accessories. Class: C.	Ophthalmic Lasers+Access ories	<b>Deferred</b> for submission of valid Full Quality Assurance Certificate and priority to consider in this application and all remainder devices shall be

					applied separately.
71.	-do-	<p>Legal Manufacturer Ret, INc 726-5, Dureungyuri-ro Ochang-eup, Cheongwon-Gu, Cheongju-si, Chungcheongbuk-do, south Korea</p> <p>FSC: Korea Date of issue 26.09.2019</p>	<b>COMPORT</b> (IOL injector). Class:B.	Ophthalmic Medical Device	<p><b>Deferred</b> for submission of technical info. of QC, clarification regarding The product applied for registration <b>on the basis of free sale certificate of Korea</b>, but the subject product name is not mentioned. The provided GMP certificate is concluded as non-conformance of directives 93/42/EEC, hence it is advised to submit the conformance/ follow-up report.</p>
72.	M/s PharmEvo (Pvt) Ltd. A-29, North Western Industrial Zone, Port Qasim Karachi-75020, Pakistan	<p><b>Legal Manufacturer:</b> Omron Healthcare Co., Ltd. 53, Kunotsubo, Teradocho, Muko Kyoto, 617-0002 Japan.</p> <p><b>Manufacturing Facility:</b> KunShan Radiant Innovation Co., Ltd. No.20, TaiHong Road, Wusong jiang Development Zone Yushan Town, KunShan city Jiangsu 215300, china.</p> <p>FSC Netherland validity</p>	<p>Omron Gentle Temp 720</p> <p>Class-B</p> <p>Shelf Life: N/A</p> <p>Code: MC-720-E</p>	Gentle Temp 720 Infrared forehead Thermometer	<b>Approved.</b>

		21-02-2024			
73.	M/s. Cardiac Care 848-C Shadman-I Lahore.  ELI-00070	<b>Legal manufacturer</b> Cyro Life, INC. Loacated at 1655 Robert Blvd, NW, Kennesaw, GA, 30144 USA  FSC USA Valid Till 14 <sup>th</sup> March, 2021	<b>Bio Glue Surgical Adhesive</b> (Glue, Surgical, Arteries Surgical adhesive/sealant, animal derived)  Class D  Shelf life: 2ml 21 months 5ml 18 months 10ml 24 months  Codes: BG3502-5G, 2ml solution syringe, 5 pack BG3515-5G, 5ml solution syringe, 5 Pack BG3510-5G, 10ml solution syringe, 5 pack	Bio Glue ® Surgical Adhesive (Bio Glue) is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery , and / or patches) to bond, seal and / or reinforce soft tissue. Bio Glue may also be applied alone to seal and or reinforce damaged parenchyma when other ligature or conventional procedures are ineffective or impractical, indicated soft tissues are cardiac, vascular, pulmonary, genitourinary, Dural, alimentary (esophageal, gastrointestina l, and colorectal,) and other abdominal (pancreatic,	<b>Approved.</b>

				splenic, hepatic and biliary). Additionally, Bio Glue is used in the fixation of surgical meshes in hernia repair.	
74.	M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi (ELI-00007)	<p><b>Legal Manufacture:</b> M/s Amsino International, Inc. 708 Corporate Center Drive, Pomona CA 91768, USA</p> <p><b>Manufacturing Site:</b> M/s Amsino Medical (Kunshan) Co. Ltd, 582 Lidu Road, Qiandeng Town, 215343 Kunshan City, China</p> <p>FSC China Valid Till 25-05-2021</p> <p>FSC Netherland Valid Till 26-04-2024</p>	<p><b>Amsino Burette Set (IV Administration Set)</b></p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Codes &amp; sizes as per FSC</p>	<b>Burette Set</b>	<b>Approved.</b>
75.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073)	<p><b>Legal Manufacture:</b> M/s Teleflex Medical 3015 Carrington Mill Blvd Morrisville, NC 27560, USA</p> <p><b>Manufacturing Site:</b> M/s Hudson Respiratory Care Tecate S. de R.L. C.V. (a Teleflex medical company) prolongacion</p>	<p><b>Weck hem-o-lok automatic clip (ML) Appliers</b></p> <p><b>AE05ML, 543965</b></p> <p><b>Class D</b></p> <p><b>Shelf Life: 03 Years</b></p> <p><b>Rs. 50,000/-</b></p>	<b>automatic clip (ML) Appliers</b>	<b>Approved.</b>

		mission eusebio kino no. 1316, rancho El Descanso tecate, Baja California C.P. 21478, Mexico  FSC USFDA Valid Till19-06-2021			
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### 15. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Tech Zone, 764 Askari 9, Zarar Shaheed Road, Cantt, Lahore,  Ware House: Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040	<b>Manufacturer:</b> GrupA Medikal Tekstil Tibbi Malzeme. Iklimlendrime.San.Ve. Tic. LTD. STI., Adalet Mah. Manas Bulvari Cd No: 47/2601 Bayrakli/Izmir Turkey  Manufacturing site: GrupA Medikal Tekstil Tibbi Malz. Iklim.San.Ve. Tic. LTD. STI., Dogus Caddessi. 3/19, Sokak. No: 6, Begos 1. Bolge, Buca-Izmir, Turkey  FSC Turkey Valid till 26.09.2022	Sterile Disposable Surgical Gown  Class A  Sizes: S, M, L, XL, XXL, XXXL  Shelf Life: 3 years.  Fee submitted: Rs. 5,000/-	Sterile, single- use gowns used in surgery	<b>Approved</b>
2.	M/s Atlantic Pharmaceuticals, 445, Sodawaterwala Building, Dr. Ziauddin Ahmed Road, Near Light	<b>Manufacturer:</b> Alliance Rubber Products SDN BHD LOT 2716 & 2720 MK 7, 14300 Nibong Tebal Pulau Pinang Malaysia	SAFEPLUS Powder Free Latex Examination Gloves Size: Small, Medium, Large, Extra large, Extra	Non-sterile, single use, powder free, natural rubber latex examination	<b>Approved</b>

	House, Karachi. (ELI:00260)	(FSC Malaysia valid till 23-05-2021)	Small  Class A  Shelf Life: 5 Years  Fee submitted: Rs. 5,000/-	glove	
3.	-do-	<b>Manufacturer:</b> Alliance Rubber Products SDN BHD LOT 2716 & 2720 MK 7, 14300 Nibong Tebal Pulau Pinang Malaysia (FSC Malaysia valid till 23-05-2021)	FINECARE Powdered Latex Examination Gloves Size: Small, Medium, Large, Extra large, Extra Small  Class A Shelf Life: 5 Years Fee submitted: Rs. 5,000/-	Non-sterile, single use, powder free, natural rubber latex examination glove	<b>Approved</b>
4.	M/s Arham Enterprises, Plot # 95, Mezzanine Floor, Kashmir Arcade, Blue Area, Islamabad  ELI: 00509	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA-CYBERG BodyCy (Knitted Shoulder Support)  Class:A Ref: 30.802 Size: S, M, L, XL, XXL  Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support Provide support and arm to the shoulder joints.	<b>Approved</b>
5.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA-CYBERG Ankle Support Knitted with Silicone Pad  Class: A Ref: 90.441 Size: S, M, L, XL, XXL  Shelf life: 5 years Fee submitted: Rs.	Orthopedic Support. Provide massage action to increase blood circulation during strains. Helps to remove hematoma and edema.	<b>Approved</b>

			5,000/-		
6.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG LumboCy CTLS1 Corset Thoraco- Lomber</p> <p>Class: A</p> <p>Ref: 40.330.03 40.330.02 40.330.01 40.330.04 40.330.05</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Helps to correct dorsal spine and helps in the treatment of Kyphosis. Provides stabilization for hyperextension in vertebral fractures of the lumber and thoracic spine</p>	Approved
7.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG LumboCy CLS1 Corset Lumbo- sacral without Belt</p> <p>Class:A</p> <p>Ref: 40.250 40.250.03 40.250.02 40.250.01 40.250.04 40.250.05</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Supports back muscles in problems of lower back (Lumbago) in association with facet joint disorders</p>	Approved
8.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey</p>	<p>MORSA- CYBERG LumboCy CPTI Corset Posturex</p> <p>Class:A</p> <p>Ref: 40.161 40.161.01 40.161.02 40.161.03 40.161.04</p>	<p>Orthopedic Support. Provides a simulative and corrective effect in postural deficiencies and mild kyphosis</p>	Approved



		valid till 19-03-2023	Shelf life: 5 years Fee submitted: Rs. 5,000/-		
9.	-do-	Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG SilBerg Silicone Heel Cushion  Class:A  Ref: 105.252.01 105.252.02 105.252.03 105.252  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Provides relaxation in Epin calcaneus and achilles tendon	Approved
10.	-do-	Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG Wrist Splint (long)  Class: A  Ref: 60.019  Size: S, M, L, XL, XXL  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Provides immobilization and constraints to the movement of wrist	Approved
11.	-do-	Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG ThermoCy Epicon Epicondylitis Bandage STD  Class: A  Ref: 50.303  Shelf life: 5 years  Fee submitted: Rs.	Orthopedic Support. Used in the treatment of epicondylitis by decreasing the load on tendons by applying compression	Approved

			5,000/-		
12.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG WoolCy YD Wool Knee Support</p> <p>Class: A</p> <p>Ref: 20.001.01 20.001.02 20.001.03 20.001.04 20.001.05</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Provide heat and temperature to the knee joint</p>	Approved
13.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG SoftCy Scap Clavícula Bandage</p> <p>Class: A</p> <p>Ref: 30.311 30.311.01 30.311.02 30.311.03 30.311.04</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support to stabilize clavícula fractures</p>	Approved
14.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG Thumb Splint</p> <p>Class: A</p> <p>Ref: 60.015</p> <p>Size: S, M, L, XL, XXL</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs.</p>	<p>Orthopedic Support. Inhibits the thumb joint and provides external support, used in De Quervain syndrome and thumb ligament problems</p>	Approved

			5,000/-		
15.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Basakşehir/Istanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG Silberg Silicone Insoles (Full)</p> <p>Class: A</p> <p>Ref: 105.250 105.250.01 105.250.02 105.250.03 105.250.04</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Reduce pain in pes cavus problem. Gives anatomic support and spread all pressure with balance on sole</p>	Approved
16.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Basakşehir/Istanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG SoftCy Arm Sling (Lux)</p> <p>Class: A</p> <p>Ref: 30.301 30.301.01 30.301.02 30.301.03 30.301.04 30.301.05</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Stabilizes the arm in the desired position to immobilize the arm shoulder</p>	Approved
17.	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Sitesi 4, ADA A Blok No. 602 KAT 6 Basakşehir/Istanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG Silberg Silicone Toe Separator</p> <p>Class: A</p> <p>Ref: 105.254.01 105.254.02 105.254.03</p> <p>Shelf life: 5 years</p>	<p>Orthopedic Support. Keeps the thumb stable especially in shoes.</p>	Approved

			Fee submitted: Rs. 5,000/-		
<b>18.</b>	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG ThermoCy Genu3 Knee Support with Flexible Stays (long)</p> <p>Class: A</p> <p>Ref: 20.103.01 20.103.02 20.103.03 20.103.04 20.103.05</p> <p>Shelf life:5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Provides collateral stabilization, protection in sports activities, indicated for strain-sprain, arthritis- bursitis and tendinitis</p>	<b>Approved</b>
<b>19.</b>	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG Lumbocy CAS1 Corset Abdominal</p> <p>Class: A</p> <p>Ref: 40.420 40.420.01 40.420.02 40.420.03 40.420.04 40.420.05</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support for abdominal area following abdominal surgeries and prevents sagging in the abdominal area following pregnancy.</p>	<b>Approved</b>
<b>20.</b>	-do-	<p>Manufacturer: MORSA MEDİKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, İkitelli Organize Sanayi Bölgesi Giyim Sanayi Site 4, ADA A Blok No. 602 KAT 6 Başakşehir/İstanbul Turkey.</p>	<p>MORSA- CYBERG NeckCy C3 Cervical Orthosis (Sponge)</p> <p>Class: A</p> <p>Ref: 12.103.01 12.103.02</p>	<p>Orthopedic Support. Inhibits the movements to relieve moderate pain of the neck. Applicable in cases of cervical disc hernia, cervical</p>	<b>Approved</b>

		FSC Turkey valid till 19-03-2023	12.103.03 12.103.04 12.103.05  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	osteoarthritis and cervical muscle pains.	
21.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG ThermoCy L3 Corset Neoprene (Abdominal)  Class: A  Ref: 40.203.01 40.203.02 40.203.03 40.203.04 40.203.05  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Provides warmth and support to the abdominal area	<b>Approved</b>
22.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG ThermoCy Genu 1 Knee Support Open Patella  Class: A  Ref: 20.101 20.101.01 20.101.02 20.101.03 20.101.04 20.101.05  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Used in patellar femoral pains, osteoarthritis and meniscus injuries	<b>Approved</b>
23.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK.	MORSA- CYBERG ThermoCy H	Orthopedic Support. Provide wrist	<b>Approved</b>

		SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	Hand Strap STD  Class: A  Ref: 60.600  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	protective support for sports activities.	
24.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG LumboCy CLS2 Corset Lumbo- sacral with Belt (short)  Class: A  Ref: 40.260.01 40.260.02 40.260.03 40.260.04 40.260.05 40.260  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Supports back muscles in problems of lower back (lumbago) in association with facent joint disorders. Helps in pain in the the sacroiliac and lumbosacral joint in cases of chronic lumbo sacral pains	<b>Approved</b>
25.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.  FSC Turkey valid till 19-03-2023	MORSA- CYBERG Silberg Met2 Silicone Metatarsal pad with fabric  Class: A  Ref: 105.260.01 105.260.02 105.260.03  Shelf life: 5 years  Fee submitted: Rs. 5,000/-	Orthopedic Support. Wedge used in between the toes and support metatarsal area.	<b>Approved</b>
26.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK.	MORSA- CYBERG ThermoCy H3	Orthopedic Support. Provide wrist	<b>Approved</b>

		<p>SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>Wrist Bandage STD</p> <p>Ref: 60.603</p> <p>Class-A</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>protective support for sports activities.</p>	
27.	-do-	<p>Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK. SAN. Tic Ltd Sti, Ikitelli Organize Sanayi Bolgesi Giyim Sanayi Sitesi 4, ADA A Block No. 602 KAT 6 Basakeshir/Istanbul Turkey.</p> <p>FSC Turkey valid till 19-03-2023</p>	<p>MORSA- CYBERG SilBerg Silicone arch support with fabric</p> <p>Ref: 105.253.01 105.253.02 105.253.03</p> <p>Class-A</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Orthopedic Support. Give support on longitudinal arch in case of impairment base</p>	Approved
28.	<p>M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi.</p> <p>ELI-00209</p>	<p><b>Legal Manufacturer:</b> M/s. D-tek s.a. Belgium Parc Initialis Rue rene Descartes, 19 BE-7000 Mons BELGIUM.</p> <p>FSC Belgium Issued on 06.02.2019</p>	<p><b>DrDOT Scanner Dr DDot Software LIC4</b></p> <p>Class A Shelf Life: N/A</p> <p>Codes: <b>Software (BE- CA02-097-15)</b> Bluescan 1 (BE- CA02-366-16)</p>	<p>The Dr Dot software is intended for the quantification of the results obtainedfor tests of the ranges BlueDot, BlueDiver dot, BlueDiver Quantrixand proposed by other manufacturers. The DrDot software has to be used in combination with the BlueScan scanner; this scanner has</p>	Approved

				been specifically developed for the reading of the strips of the above-mentioned ranges.	
29.	M/s Horizon Group of Company 603-Kamran Block Allama Iqbal Town, Lahore  ELI-00140	<b>Legal Manufacturer:</b> M/s Baoying Country Fukang Medical Applicane Co Ltd Guangyang Road HuangCheng Town Industrial Area Baoying Country Yangzhou Jiangsu, China FSC China Valid till 21th Novemver,2020	Alcohol Pads  Class-A  Shelf life: 3 years Models 3x3cm, 3x6cm, 6x6cm, 8x4cm, 9x4cm, 8x8cm, 9x9cm ,10x12cm,10x15 cm,12x15cm, 15x15cm,10x20c m,12x20cm,15x 20cm	To be used for cleansing and disinfecting non-invasive medical device.	<b>Approved</b> subject to provision of valid FSC before issuance of registration letter.
30.	M/s. Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi <b>(ELI-00238)</b>	Legal Manufacturer: M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021).	<b>OXYMAX-SURGI-TAPE</b> Surgical paper Tape.  Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Surgical paper Tape	<b>Approved</b> subject to provision of justificatio n of stability study and approved labelbefore issuance of registration letter.
31.	<b>-do-</b>	<b>Legal Manufacture:</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021).	<b>OXYMAX-</b> Waycare Eye Pad.  Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Waycare Eye Pad	<b>Approved</b> subject to provision of justificatio n of stability study and approved label before



					issuance of registration letter.
32.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021)	<b>OXYMAX-</b> IV Cannula Dressing. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	IV Cannula Dressing	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.
33.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Absorbent Pad. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Absorbent Pad	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.
34.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Self Adhesive Wound Dressing. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Self Adhesive Wound Dressing	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.

35.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Surgitrans Transparent PE Tape Roll. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Surgitrans Transparent PE Tape Roll	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.
36.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Transparent Film Dressing. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Transparent Film Dressing	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.
37.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Non-Woven Fabric Adhesive Roll. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Non-Woven Fabric Adhesive Roll	<b>Approved</b> subject to provision of justification of stability study and approved label before issuance of registration letter.
38.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District,	<b>OXYMAX</b> Surgioplast First Aid Bandage. Codes & Sizes as per FSC.	Surgioplast First Aid Bandage	<b>Approved</b> subject to provision of justification

		Guangzhou, China FSC China Valid Till (08-01-2021)	<b>Class-A.</b> claimed shelf life: 05-years.		n of stability study and approved label before issuance of registration letter.
39.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Paraffin Gauze Dressing with Chlorhexidine.10  Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Paraffin Gauze Dressing with Chlorhexidine. 10	<b>Approved</b> subject to provision of justificatio n of stability study and approved label before issuance of registration letter.
40.	-do-	<b>Legal Manufacturer</b> M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	<b>OXYMAX</b> Wound Closure strip. 12. Codes & Sizes as per FSC. <b>Class-A.</b> claimed shelf life: 05-years.	Wound Closure strip	<b>Approved</b> subject to provision of justificatio n of stability study and approved label before issuance of registration letter.
41.	M/s Sudais Associates, Sudais House Street No.7, House No.1 Khan Bahadur Colony Duran Pur Peshawar  ELI: 00031	Legal Manufacturer  Mexpo International Inc. 2828 Faber Street, Union City CA 94587, USA Production Facility: TG Medical Sdn. Bhd Lot 5091, Jalan Teratai, batu 5. Off	<b>VARISOCKS</b> (Medical elastic antiembolism stocking).  Class-A.	Medical elastic antiembolism stocking helps in varicose veins by improvement in circulation	<b>Approved.</b>

		Jalan Meru, 40150 Klang Selangor. FSC: USFDA. Valid till: 15 <sup>th</sup> October, 2021			
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# **16. CASES APPROVED IN DIFFERENT MEETINGS OF MDB SUBJECT TO PROVISION OF DOCUMENTS.**

Following applications for registration of Medical Devices for import were placed before the MDB in its 15th meetings and approved subject to provision of documents. The firm has submitted the documents:-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	M/s. Surgi World Office No. 303, Muhammadia Plaza, College Road, Rawalpindi.  (ELI-00212)	<b>Legal Manufacturer:</b> Bard Access System, Inc. 605 North 5600 West Salt Lake City, UT USA.  <b>Manufacturing Sites:</b> Bard Reynosa S.A. DE C.V. BLVD. MONTBELLO No. 1, PARQUE INDUSTRIAL COLONIAL REYNOSA, Tamaulipas, Mexico  FSC USA (FDA) Valid till July, 02, 2020	<b>X- PORT™ isp Implantable port</b>  <b>0607500, 0607510, 0607520, 0607525, 0607530, 0607540, 0607550, 0607555, 0607560, 0657500, 0657510, 0657520, 0657525, 7707540, 7757540</b>  Class D  Shelf Life 5 years Rs.50,000/-	The X- port isp™ Implantable ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.	<b>MDB approved the products at Sl. No.1-6 subject to provision of updated or valid LOA</b>
2.	-do-  <b>Evaluator:</b> AD-III	<b>Legal Manufacturer:</b>  Angiomed GmbH & Co. Medizintechnik KG, Wachausstrasse 6, 76227 Karlsruhe, Germany  FSC Germany	<b>Angiomed PTFE COATED GUIDE WIRE</b>  02200020 02200030 02200040 02200050 02200080 02220020 02220040 02220050	A guide wire, for interventional procedures.	<b>MDB approved the products at Sl. No.1-6 subject to provision of updated or valid LOA</b>

		Issue date 22.01.2019	02250040 02250050 02250060 02250080 02270050 02290020 02290040 02290050 02310020 02310030 02310040 02310050 02310057 02310060 02310070 02310080 02310090 02310100 02310110 02330030 02330040 02330050 02330060 02330070 02330080 03000050 03000060 03020050 03020060 03040050 03060050 03060060 03070040 03070050 03100060 03300040 03300050 03350030 03350040 03350050 03370050 03390040 03390050 03410020 03410030 03410040 03410050 03410051 03410055 03410060 03410070 03410080 03430020		
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			03430030 03430040 03430050 03430080 03670050  Class D  Shelf Life 3 years		
3.	-do-  <b><u>Evaluator:</u></b> AD-III	<b>Legal Manufacturer:</b> Angiomed GmbH & Co. Medizintechnik KG, Wachausstrasse 6, 76227 Karlsruhe, Germany  FSC Germany Issue date 22.01.2019	<b>Angiomed PERCUTANEOUS KIDNEY DRAINAGE</b>  55000010 55000030 55000040 55000050 55000070 55000080 55000090  Class C  Shelf Life 3 years  Rs.50,000/-	A catheterization method use to drain the kidneys, when an obstruction has blocked the urinary passage.	<b>MDB approved the products at Sl. No.1-6 subject to provision of updated or valid LOA</b>
4.	-do-  <b><u>Evaluator:</u></b> AD-III	<b>Legal Manufacturer:</b> Angiomed GmbH & Co. Medizintechnik KG, Wachausstrasse 6, 76227 Karlsruhe, Germany  FSC Germany Issue date 22.01.2019	<b>Angiomed PERCUTANEOUS KIDNEY DRAINAGE</b>  55000010 55000030 55000040 55000050 55000070 55000080 55000090  Class C  Shelf Life 3 years  Rs.50,000/-	A catheterization method use to drain the kidneys, when an obstruction has blocked the urinary passage.	<b>MDB approved the products at Sl. No.1-6 subject to provision of updated or valid LOA</b>
5.	-do-  <b><u>Evaluator:</u></b> AD-III	<b>Legal Manufacturer:</b> Bard Access System, Inc.605 North 5600 WestSalt Lake City, UT USA. <b>Manufacturing</b>	<b>BROVIAC® Central Venous Catheter</b> <b>0600520</b> <b>0600540</b> <b>0600040</b>  Class D	BROVIAC® CENTRAL VENOUS CATHETERS are designed for long-term vascular access and for use in	<b>MDB approved the products at Sl. No.1-6 subject to provision of updated or</b>

		<b>Sites:</b> Bard Reynosa S.A. DE C.V. BLVD. MONTBELLO No. 1, PARQUE INDUSTRIAL COLONIAL REYNOSA, Tamaulipas, Mexico  BARD SHANNON LIMITED, SAN GERONIMO INDUSTRIAL PARK, LOT No. 1, ROAD No. 3, KM 79.7 HUMACAO, PR USA 00791  FSC USA (FDA) Valid till July, Feb.13, 2021	Shelf Life 5 years Rs.50,000/-	patients that lack adequate peripheral venous access.	<b>valid LOA</b>
6.	-do-  <b><u>Evaluator:</u></b> AD-III	<b>Legal</b> <b>Manufacturer:</b> Bard Access Systems Inc. 605 North 5600 West Salt Lake City Ut, USA 84116  <b>Manufacturing</b> <b>Sites:</b> BARD SHANNON LIMITED, SAN GERONIMO INDUSTRIAL PARK, LOT No. 1, ROAD No. 3, KM 79.7 HUMACAO, PR USA 00791  FSC USA (FDA) Valid till July, Feb.13, 2021	<b>HICKMAN®</b> <b>CENTRAL</b> <b>VENOUS</b> <b>CATHETER</b> <b>0600310, 0600320,</b> <b>0600570, 0600580,</b> <b>0600600, 0600620,</b> Class D Shelf Life 5 years Rs.50,000/-	HICKMAN ® CENTRAL VENOUS CATHETER are designed for long-term vascular access and for use in patients that lack adequate peripheral venous access. They are available in single, dual and triple lumen catheters. They are designed for the administration of I.V fluids parenteral.	<b>MDB</b> <b>approved the</b> <b>products at</b> <b>Sl. No.1-6</b> <b>subject to</b> <b>provision of</b> <b>updated or</b> <b>valid LOA</b>

7.	M/s SES Associates, 148-Ejaz Park Model Town Link Road, Lahore (ELI-00041)	<b>Legal Manufacturer/ Manufacturing Site:</b> M/s QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16 D-21423 Winsen, Germany  (FSC Germany Issuance Date 13-08-2013)	MAGMA Rapamycin-Eluting Coronary Stent System  Class D Shelf Life: 18 months Fee: 50,000/-	Drug eluting Coronary Stent System	<b>Approved</b>
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#### **17. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

**Following applications for registration of Medical Devices for import were placed before the MDB in its 19th meetings and deferred for provision of document. Now the firm has submitted the shortcomings:**

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<b>S.#</b>	<b>Name of Firm (s)/Importer</b>	<b>Name of Manufacturer</b>	<b>Name of Medical Device</b>	<b>Brief Description</b>	<b>Decision</b>
1.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)  <b>Evaluator:</b> AD-IV [1581]	<b>Legal Manufacturer:</b> Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 <b>Manufacturing Site:</b> Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland valid till 24-05-2022)	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)  Class D Shelf Life: 3 Years Codes as Per FSC Ireland No. CFS008539 dated 24-05-2017 Fee submitted: Rs.50,000	Indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries. Sterile, single-use	Approved
2.	-do-  <b>Evaluator:</b> AD-IV [1571]	<b>Legal Manufacturer:</b> Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN	Attain Command + SureValve guide catheter for left heart delivery  Class D	Designed to facilitate lead implantation in the left heart via the coronary sinus.	Approved



		55432, USA  <b>Manufacturing Site:</b> Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland Valid till 05-12-2023)	Codes: 6250VI-EH 6250VI-EHXL 6250VI-45S 6250VI-50S 6250VI-57S 6250VI-MB2 6250VI-MB2X 6250VI-MP 6250VI-MPR 6250VI-AM 6250VI-MPX 6250VI-3D  Shelf Life: 18 Months	Sterile, single-use	
3.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. (ELI-00209)  <b>Evaluator:</b> AD-III	<b>Legal Manufacturer:</b> Nova biomedical 200 Prospect Street Waltham. MA 02454. USA.  (FSC valid 15-03-2024)	<b>Stat Sensor Xpress Creatinine Meter System</b> Stat Sensor Xpress Creatinine Meter System Class B Shelf Life: 24 Months Codes L: Rs.25,000/-	The system used in the quantitative determination of Creatinine (creat) in capillary, venous, and arterial whole blood.	Approved .
4.	M/s M Islam & Sons Near Ghee Mills, Tehsil Dargai, District Malakand, KPK, Pakistan  ELI-00594	M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng office Shan County Heze City Shandong Province, China  FSC China Dated: 27.02.2022	RTMED Chrome Catgut Sutures Class-D Shelf life: 5 years <b>Sizes &amp; codes</b> USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 <b>Needle shape:</b> Round bodied, straight, cutting, reverse, taper cutting, <b>Needle curvature:</b> ½ circle, 3/8 circle, straight	Catgut chrome sutures are intended for use in general soft tissue closing and/or ligation; in particular in general surgery, gastrointestinal surgery, gynecology, obstetrics, urology, ophthalmic surgery	Approved

5.	-do- <b>Evaluator:</b> AD-III	M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng office Shan County Heze City Shandong Province, China  FSC China Dated: 27.02.2022 Reference country FSC Spain issuance 16-03-2020	RTMED Polyglactin Absorbable surgical sutures (PGLA) Class-D Shelf life: 5 years <b>Sizes &amp; codes</b> USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 <b>Needle shape:</b> Round bodied, straight, cutting, reverse, taper cutting, <b>Needle curvature:</b> ½ circle, 3/8 circle, straight	Polyglactin Absorbable surgical sutures (PGLA) are intended for use in general soft tissue closing and/or ligation; in particular in general surgery, gastrointestinal surgery, gynecology, obstetrics, urology, ophthalmic surgery	Approved
6.	M/s. Iqbal and Company Alfalah manzil Opp. National Police Foundation Street No. E-11/4, Islamabad. ELI-00117.  <b>Evaluator:</b> AD-III	<b>Legal Manufacturer:</b> M/s MEDICAL COMPONENTS INC DBA-Medcomp 1499 DELP DRIVE HARLEYSVILLE, PA USA 19438  FSC GERMANY Issued date 28 June, 2019	Dura lock-C  (CATHETR LOCK SOLUTION)  PFDLC 504 PFDLC 530 PFDLC 546  Class B FEE SUBMITTED RS 25,000/-  Shelf Life 2 years	Dura Lock-C™ is indicated for use in maintaining patency Of Hemodialysis Catheters	Approved
7.	M/s Krestacorp, 76-C, 3 <sup>rd</sup> Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 07, Karachi  <b>Evaluator:</b> AD-III	<b>Legal Manufacturer/ Manufacturing Site:</b> M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor DarulTakzim, Malaysia  (FSC Malaysia Valid Till 13-02-2021) FSC reference	Feel Studded condoms  Natural rubber latex Male Condoms  Class C Shelf Life: 5 Years  Sizes & Codes: P53D  Rs.50,000	Natural Rubber Latex Condoms is a non-Sterile, Single use device made of natural rubber latex, lubricated with silicone oil. It is Packed in a rolled-up form in an individual heretically sealed square foil sachet comprises of polyester/ aluminum/ Polyethylene/ LDDPE. Foiled	Approved

		country MHRA issuance 30-01-2019		condoms are packaged in cardboard outer boxes. It is used for contraception and prevention of sexually transmitted disease.	
8.	M/s. Hashir Surgical Services, Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar.  (ELI-00075)  <b><u>Evaluator:</u></b> AD-IV  [759-P]	<b>Manufacturer:</b> M/s. USM Healthcare Medical Devices Factory JSC Lot I-4b-1.3, N3 Street, Saigon Hi-tech Park, Long Thanh My Ward, District 9, Ho Chi Minh City, Vietnam,  FSC Vietnam valid till 06-10-2022	Favocath U (Set of I.V Catheter and Injection stopper)  Class B  Code:- Codes as per FSC Vietnam dated 07-10-2019  Shelf Life: 5 years.  Fee submitted: Rs. 25,000/-	Sterile, single-use I.V catheter with valve and injection stopper	The MDB deferred the product subject to provision of reference country Free Sale Certificate or inspection of manufacturer abroad.

**18. 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 of MDB
1.	M/s Zenith International, Room No. 104, Tahir Plaza A/20 Block 7&8	Legal Manufacturer M/s Blue Sail Medical Co., Ltd No, 21 Qingtian Road, Qilu	<b>PERFECT</b> (Disposable Vinyl Examination Gloves, Non-Sterile, Powdered).	Disposable Vinyl Examination Gloves, Non-Sterile, Powdered.	<b>Approved</b> subject to provision valid ISO.13485 Certificate.

	K.C.H.S.U Karachi. <b>ELI: 00090.</b>	Chemical Industrial Park, Zibo City Shandong Province, China FSC: China	Class-A Shelf Life: 60 months  Rs. 5,000/-		
2.	<b>-do-</b>	Legal Manufacturer M/s Blue Sail Medical Co., Ltd No, 21 Qingtian Road, Qilu Chemical Industrial Park, Zibo City Shandong Province, China FSC: China	<b>BLUE SAIL+</b> Disposable Nitrile Examination Gloves, Non- Sterile, Powder Free Class-A Shelf Life: 60 months.	Disposable Nitrile Examination Gloves, Non- Sterile, Powder Free.	<b>Approved</b> subject to provision valid ISO.13485 Certificate.
3.	<b>-do-</b>	<b>Manufacturer:</b> M/s Hospital & Hemocare Medical Devices Co., Ltd., No. 188 East of Jingwu Road, West Side, Ye Ya Science and Technology Park, Jianhu, Jiangsu, China	<b>PERFECT FINE,</b> Disposable Suction Catheter. Shelf Life: 60 months. Class-B.	Disposable Suction Catheter	<b>Approved</b> subject to inspection of manufacturer abroad and provision valid ISO.13485 & Full QA Certificate.
4.	<b>M/s. Freesia Enterprises</b> Address: First Floor,104 Dawn Plaza, Bank Road, saddar, Rawalpindi	<b>Legal Manufacturer:</b>  M/s. <b>WRP Asia Pacific Sdn.Bhd</b> Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia.	<b>PROFEEL</b> powder free latex surgical gloves sterile.  Class: B  Shelf Life: 03 Years	Profeel ® NR Latex Surgical Gloves (powder free and sterile) is intended for surgical work and for single use only.	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A, DRAP.
5.	<b>-do-</b>	<b>Legal Manufacturer:</b>  M/s. <b>WRP Asia Pacific Sdn.Bhd,</b> Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900	<b>COMFIT-NR</b> Latex Surgical gloves powdered sterile  Class: B  Shelf Life: 03 years	Comfit NR Latex Surgical Gloves (powered and sterile) is intended for surgical work and for single use only. The surface powder should be removed by a sterile prior to	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A,

		Sepang, Selangor Darul Ehsan, Malaysia		undertaking operation procedures in order to minimize the risk of any adverse tissue reaction.	
6.	-do-	<b>Legal Manufacturer:</b> M/s. <b>WRP Asia Pacific Sdn.Bhd</b> Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia	<b>COMFIT PREMIUM-NR</b> latex surgical gloves powdered sterile  Class: B  Shelf Life: 03 Years	Comfit NR Latex Surgical Gloves (powered and sterile) is intended for surgical work and for single use only. The surface powder should be removed by a sterile prior to undertaking operation procedures in order to minimize the risk of any adverse tissue reaction.	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A,
7.	-do-	Legal Manufacturer: Deri OSB Mahallesi Yn Sanayi Cad No. 13 Tuzla/Istanbul Turkey. FSC: Turkey Date of issue: 03.04.2017	<b>NASAL OXYGENCANN ULA</b> (Pediatric/ Adult)  Class-B	Nasal Oxygen Cannula Pediatric/Adult. products in the group as a 'family' should be applied separately.	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A and shelf life
8.	-do-	<b>Legal Manufacturer:</b> M/s. <b>PLASTI-MED</b> Deri OSB Mahallesi Yn Sanayi Cad. No: 13 Tuzla/Istanbul Turkey. FSC Turkey Date of Issue: 3 <sup>rd</sup> April,2017	<b>NEBULIZER SET</b> Pediatric/Adult Code: Class: B	It is used in the treatment of patients with respiratory problems and for the inhalation of drugs with patients with severe asthma. should be applied separately.	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A and shelf life
9.	-do-	<b>Legal Manufacturer:</b> Lot 1, Jalan 3, Kawasan Perusahaan bandar Baru Salak Tinggi, 43900 Sepang,	<b>PROFEEL DHD™ EXTRA</b> Protection powder free Latex Surgical Gloves  Class—B	Specially designed for specialists who demand extra sensitivity in the fingertips for micro and ophthalmic surgeries. With	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of

		Selangor Darul Ehsan Malaysia  FSC: Malaysia Date of issue 21 <sup>st</sup> March, 2011	Shelf Life: 3 years	WRP's new Profeel DHD polyisoprene Surgical Gloves, you can enjoy the fit, feel and comfort of natural rubber latex in a 100% latex free product, Powder free feature eliminates powder induced irritation and powder stains Environmentally friendly and biodegradable Damp Hand Donning (DHD).	fee deposited attested by Director of B&A,
10.	-do-	<b>Legal Manufacturer:</b>  M/s. <b>WRP Asia Pacific Sdn.Bhd</b> Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia	<b>PROFEEL</b> double gloving system latex powder free latex surgical gloves sterile.  Class: B Shelf Life: 03 Years	Profeel double gloving system latex powder free latex surgical gloves sterile	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A,
11.	-do-	<b>Legal Manufacturer:</b>  Deri OSB Mahallesi Yn Sanayi Cad No. 13 Tuzla/Istanbul Turkey. FSC: Turkey Date of issue: 03.04.2017	<b>OXYGEN MASK.</b> Adult/Pediatric  Class-B	It is used to give oxygen to treat the potentially harmful and deadly effect of hypoxemia	<b>Approved</b> subject to inspection of manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A and shelf life
12.	M/s Hayat Kimya Pakistan (Pvt), Ltd Plot No. 279, 280 & 281, Phase II, M3 Industrial Citry Zone (FIEDMC), Tehsil Chak	<b>Legal Manufacturer:</b> Hayat Kimya Sanayi A. S (Headquarter) Mahir Iz Card No. 25, 34662 Uskudar/ Istanbul. <b>Factory site:</b> Sepetlipinar Mah.Hayat	<b>EVONY</b> Surgical Mask with Soft Elastic Ears Green (Disposable Surgical Mask- Non-sterile)  Class-A Shelf Life: 03 years	Surgical Mask with Soft Elastic Ears Green (Disposable Surgical Mask- Non-sterile)	<b>Approved</b> subject to provision of Full QA Certificate.

	ELI: 00605.	Cad.No.! Basiskele.Kocaeli FSC: Istanbul Date of issue: 04-07-2020.			
13.	M/s 3A Nutra, 12-FI, Johar Town, Lahore  ELI: 00134.	Legal Manufacture: M/s Changzhou Baidelin Health Material Co., Ltd No. 218, Sanhe road Sanhekou Development Zone Zhenglu Town, Tianning District, Changzhou city, Jiangsu Province, China FSC: China Valid till: 2021.05.18	<b>DISPOSABLE MEDICAL</b> Face Mask  (Disposable Medical Face Mask/ 3 ply face mask  Class-A  Shelf Life: 3 years	This medical device covers mouth, nose and chin to prevent the transmission of infectious agents amongst people, hospital staff and the patients. The product is meant to be used by healthcare professionals and the general public for their personal protection. This product prevents acquiring any infection from and prevents the entry of dust and other airborne particles into the mouth and nose of an individual.	<b>Approved.</b>
14.	M/s A.M Distributors 4 <sup>th</sup> Floor, Plot 37-C, Bukhari Commercial Area Lan & Phase VI, DHA, Karachi  ELI: 00248	<b>Legal Manufacturer:</b>  HENAN Medical Technology Co., Ltd Huayuan Road NO, 39, Jinshui District, Zhengzhou City, Henan Province China  FSC: China  Valid till: 26.07.2021	<b>COVER X®</b> Disposable Drapes and Gowns  (6307-9090-4818- 9000)  Class-A  Shelf Life: 5 years	Cover X ® Surgical Disposable sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings. Cover X ® Surgical Disposable Sterile surgical gowns are worn the scrub suit of the operation team during surgical procedures to maintain a sterile surgical field and reduce the risk of transmission of	<b>Approved.</b>

				pathogens to both patients and staff.	
15.	M/s. AL-Walli Care Concepts 86-Allama Iqbal Road Garhi Shahu Lahore  ELI-00386	<b>Legal Manufacturer:</b> TG Medical SDN BHD lot 5091, jalan teratai, batu 5, off jalan meru, 41050 klang 88aiwan88r MALAYSIA. Manufacturer/ Distributor: Mexpo International Inc.2828 Faber Street Union City CA 94587-1204, USA FSC: Malaysia validtill: 31.01.20.	<b>NITRILE</b> Powdered Surgical Gloves  (Surgical Gloves)  Class-B	Surgical Gloves	<b>Approved</b> subject to provision of valid FSC of USFDA and shelf life  Firm shall apply separately for powder free gloves.
16.	-do-	<b>Legal Manufacturer:</b> TG Medical SDN BHD lot 5091, jalan teratai, batu 5, off jalan meru, 41050 klang 88aiwan88r MALAYSIA. Manufacturer/ Distributor: Mexpo International Inc.2828 Faber Street Union City CA 94587-1204, USA FSC: Malaysia validtill: 31.01.20.	<b>LATEX</b> Powdered Surgical Gloves  (Surgical Glove)  Class- B	Surgical Gloves.	<b>Approved</b> subject to provision of valid FSC of USFDA and shelf life  Firm shall apply separately for powder free gloves.
17.	M/s Sudais Associates, Sudais House Street No.7, House No.1 Khan Bahadur Colony Duran Pur Peshawar  ELI: 00031	<b>Legal Manufacturer</b> Mexpo International Inc. 2828 Faber Street, Union City CA 94587, USA Production Facility: TG Medical Sdn.	<b>LATEX SURGICAL</b> Powder Free Gloves  Class-B Shelf Life 5 years	Latex Surgical Powder Free	<b>Approved</b> subject to submission of EPSPs.



		Bhd Lot 5091, Jalan Teratai, batu 5. Off Jalan Meru, 40150 Klang Selangor. FSC: USFDA. Valid till: 15 <sup>th</sup> October, 2021.			
18.	-do-	Legal Manufacturer Mexpo International Inc. 2828 Faber Street, Union City CA 94587, USA Production Facility: TG Medical Sdn. Bhd Lot 5091, Jalan Teratai, batu 5. Off Jalan Meru, 40150 Klang Selangor. FSC: USFDA. Valid till: 15 <sup>th</sup> October, 2021	<b>LATEX SURGICAL</b> Powdered Gloves. Class-B Shelf Life 5 years	latex surgical Powdered Gloves.	<b>Approved.</b>
19.	<b><u>M/s. A.Feroz &amp; Co;</u></b> Medicine Street No.1 Marriot Road, <b>Karachi.</b> <b><u>(ELI- 00066)</u></b>	<b>Legal Manufacturer:</b> M/s. Supermax Glove Manufacturing Sdn Bhd <b>Manufacturing Site:</b> Lot 38, Putra Industrial Park, Bukit Rahman Putra , 47000 Sungai Buloh , Selangor Darul Ehsan, Malaysia Lot 42, Putra Industrial Park Bukit Rahman Putra 47000 Sungai Buloh Selangor Darul Ehsan Malaysia <b>Production Site:</b> Maxter Glove Manufacturing Sdn. Bhd Lot	<b>SUPERMAX-</b> Non-Sterile Nitrile Examination Gloves, Powder Free Class: A	The Non-Sterile Nitrile Examination Gloves, Powder Free is a medical device intended to protect the hand or part of the hand of the user. It is intended for single use only. The Non-Sterile Nitrile Examination Gloves, Powder Free are usually used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures and for laboratory purposes.	<b>Approved</b> subject to provision of original agency agreement, DoC and EPSP and shelf life

		6070, Jalan Haji Abdul Manan 6 <sup>th</sup> Miles off Jalan Meru, 41050 Klang, Selangor, Darul Ehsan Malaysia			
20.	-do-	<p><b>Legal Manufacturer:</b> M/s. Supermax Glove Manufacturing Sdn Bhd</p> <p><b>Manufacturing Site:</b> Lot 38, Putra Industrial Park, Bukit Rahman Putra, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia</p> <p><b>Production Site:</b> Maxter Glove Manufacturing Sdn. Bhd Lot 6070, Jalan Haji Abdul Manan 6<sup>th</sup> Miles off Jalan Meru, 41050 Klang, Selangor, Darul Ehsan Malaysia</p>	<b>SUPERMAX-Sterile LATEX SURGICAL</b> Gloves. Class-B	The Sterile Nitrile Examination Gloves, Powder Free is a medical device intended to protect the hand or part of the hand of the user. It is intended for single use only.	<b>Approved</b> subject to provision of original agency agreement, DoC and EPSP and shelf life
21.	<b>M/s A.M Distributors;</b> 4 <sup>th</sup> Floor, Plot 37-C, Bukhari Commercial Area Lane & Phase VI, DHA, <u><b>Karachi.</b></u> <u><b>ELI: 00248.</b></u>	<p><b>Legal Manufacturer:</b></p> <p>HENAN Medical Technology Co., Ltd Huayuan Road NO, 39, Jinshui District, Zhengzhou City, Henan Province China</p>	<b>COVER-X®</b> Disposable Gowns & Drapes. Class-A	Cover X ® Surgical Disposable sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings. Cover X ® Surgical Disposable Sterile surgical gowns are worn the scrub suit of the operation team during surgical procedures to maintain a sterile surgical	<b>Approved.</b>

		FSC: China Valid till: 26.07.2021		field and reduce the risk of transmission of pathogens to both patients and staff.	
22.	M/s 3A Nutra, 12-FI, Johar Town, Lahore. <b><u>ELI: 00134.</u></b>	Legal Manufacture:  M/s Changzhou Baidelin Health Material Co., Ltd No. 218, Sanhe road Sanhekou Development Zone Zhenglu Town, Tianning District, Changzhou city, Jiangsu Province, China  FSC: China Valid till: 2021.05.18	<b>MEDICAL</b> face mask. (Disposable Medical 3-ply face mask) Class-A.	Face mask	<b>Approved</b> subject to provision of justifiable stability study data for claimed shelf life.
23.	<b>M/s United Healthcare,</b> Plot No. 330, 2 <sup>nd</sup> Floor, DMCH, Bahadurabad, <b><u>Karachi.</u></b>	Legal Manufacturer: M/s. Jiangsu Jaysun Glove Co., Ltd No. 199 Jianling Avenue, SuQian economic and technological development zone, Suqian Jiangsu, China FSC : China Valid till: 22-7- 2021	Safety Nitrile Examination Glove (Synthhetic Rubber, Non- Sterile.)  Class A	Safety Nitrile Examination Glove (Synthhetic Rubber, Non-Sterile.)	• <b>Deferred;</b> firm asked to provide the original and valid agency agreement & FSC, certifications of ISO-13485, CE- Mark/ Product Quality Assurance, justifiable stability study data, technical info. Regarding manufacturing & QC, description of key functional elements, labeling & packaging details as per Form-7A. In case of failure to comply, the case will be considered for rejection by MDB.

24.	-do-	Legal Manufacturer: M/s. Jiangsu Jaysun Glove Co., Ltd No. 199 Jianling Avenue, SuQian economic and technological development zone, Suqian Jiangsu, China FSC : China Valid till: 22-7-2021	Safety-Latex Examination Glove (Natural Rubber, Non-Sterile) Class: A	Safety-Latex Examination Glove (Natural Rubber, Non-Sterile)	<ul style="list-style-type: none"> <li>• <b>Deferred;</b> firm asked to provide the original and valid agency agreement &amp; FSC, certifications of ISO-13485, CE-Mark/ Product Quality Assurance, justifiable stability study data, technical info. Regarding manufacturing &amp; QC, description of key functional elements, labeling &amp; packaging details as per Form-7A. In case of failure to comply, the case will be considered for rejection by MDB.</li> </ul>
25.	M/s Batla Impex, Shop. 40, Namco Centre, Cambell Street, <b><u>Karachi.</u></b> <b>-2656-S-(MD)</b>	Legal Manufacturer: Zibo Eastmed Healthcare Products Co. Ltd. No. 118 Huaguang Road, Zhangdian District Zibo 255000 Shandong China.	<b>NEW GOLDEN</b> Sterile Nebulizer Mask.  <b>Class B</b>	Sterile Nebulizer Mask	<b>Approved</b> subject to provision of original agency agreement and valid free sale certificate RRA (UK) and shelf life.
26.	-do-	Legal Manufacturer: Zibo Eastmed Healthcare Products Co. Ltd. No. 118 Huaguang Road, Zhangdian District Zibo 255000 Shandong China.	<b>NEW GOLDEN</b> Sterile Oxygen Mask.  Class B	Sterile Oxygen Mask	subject to provision of original agency agreement and valid free sale certificate RRA (UK) and shelf life

27.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi  (ELI-00099) 944-P-(MD)	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Laryngeal Mask Airway</b>  (Laryngeal Mask Airways)  Class: B  Shelf Life: 05 years  Rs. 25,000/-	A laryngeal mask airway is a device inserted into the patient's trachea through the mouth to maintain an open airway. It is used to assist the delivery of anaesthetic gases or air to and from the patient.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
28.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Gel Laryngeal Mask Airway</b>  Class: B Shelf Life: 05 years  Rs.25,000/-	A gel laryngeal mask airway is a device inserted into the patient's trachea through the mouth to maintain an open airway. It is used to assist the delivery of anaesthetic gases or air to and from the patient.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
29.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Oxygen Mask.</b>  Class: B Shelf Life: 05 years  Rs.25,000/-	Oxygen mask is a device clinically used for supporting oxygen or other medical gas for patients. It is used to cover patient's face and support oxygen and gas by oxygen tube.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
30.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Nasal Cannula</b>  Class: B  Shelf Life: 05 years  Rs.25,000/-	Nasal cannulas are devices clinically used for delivering oxygen or other medical gas for patients. It is used to insert into the patient's nose and deliver oxygen or other medical gas by oxygen tube.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.

31.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL HME for Tracheostomy Patient.</b>  Class: B Shelf Life: 05 years Rs.25,000/-	HME For Tracheostomy Patient is a dedicated HME designed for use in breathing systems in patient with tracheostomy, for the protection of heat and moisture	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
32.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Nebulizer.</b>  Class: B Shelf Life: 05 years Rs.25,000/-	Nebulizer is used to deliver aerosolized medication to the lungs	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
33.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Breathing Circuit Non-Invasive Disposable</b>  Class: B Shelf Life: 05 years. <b>Rs.25,000/-</b>	Breathing Circuit is used to transfer gas between the patient and the anesthesia machine, CPAP machine, BiPAP machine and the ventilator	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
34.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou,	<b>EMEDICAL Suction Tube.</b>  Class: B Shelf Life: 05 years Rs.25,000/-	Suction Tube is used for suctioning sputum for patient in medical units, collection type contains collecting tank for gathering of sputum sample.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.

		Guangdong,China, 516123.			
35.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	<b>EMEDICAL Breathing Circuit Catheter Mount.</b>  Class: B  Shelf Life: 05 years  Rs.25,000/-	Catheter Mount is used to connect Breathing Circuit with ETT or Laryngeal Mask Air way	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
36.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	<b>EMEDICAL Breathing Circuit with Heated wire isposable</b>  (Breathing Circuit with Heated Wire Disposable) Class: B Shelf Life: 05 years.  Rs.25,000/-	Breathing Circuit is used to transfer gas between the patient and the anesthesia machine and the ventilator	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
37.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	<b>EMEDICAL Breathing Circuit With Water Traps Disposable.</b>  Class : B  Shelf Life: 05 years  Rs.25,000/-	Breathing Circuit is used to transfer gas between the patient and the anesthesia machine and the ventilator	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
38.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer</b>	<b>EMEDICAL Breathing Circuit.</b>  Class: B	The connectors which are used to assemble the circuit like straight connectors, Elbow connectors, Y	<b>Approved</b> subject to provision of justifiable stability study data and FSC of

		<b>Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	Shelf Life: 05 years Rs.25,000/-	connectors, Machine end connectors	country of origin.
39.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Breathing Circuit Expandable Disposable</b>  Class: B  Shelf Life: 05 years. Rs.25,000/-	Breathing Circuit is used to transfer gas between the patient and the anesthesia machine and the ventilator	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
40.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Breathing System Filter Anti-bacterial/viral</b>  Class: B  Shelf Life: 05 years.  Rs.25,000/-	Breathing System Filter is a dedicated filter designed for use in breathing systems in anesthesia and intensive care, for the protection of the patient, hospital personnel and the equipment from potential microbial contamination.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
41.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL HME&amp; Antibacterial/Viral Filter</b>  Class: B Shelf Life: 05 years Rs.25,000/-	Breathing System Filter is a dedicated filter designed for use in breathing systems in anaesthesia and intensive care, for the protection of the patient, hospital personnel and the equipment from potential microbial contamination.	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.
42.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical	<b>EMEDICAL Breathing Circuit Disposable.</b>	Breathing Circuit is used to transfer gas between the patient and the	<b>Approved</b> subject to provision of justifiable



		(Huizhou) Ltd <b>Manufacturer</b> <b>Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	Class: B Shelf Life: 05 years  Rs.25,000/-	anesthesia machine and the ventilator	stability study data and FSC of country of origin.
43.	-do-	<b>Legal Manufacturer:</b> M/s. Excellentcare Medical (Huizhou) Ltd <b>Manufacturer</b> <b>Site:</b> Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	<b>EMEDICAL Anesthetic Face Mask</b>  <b>Class-B</b> <b>Shelf Life: 5 years</b> <b>Rs.25,000/-</b>	<b>Anesthetic Face Mask</b>	<b>Approved</b> subject to provision of justifiable stability study data and FSC of country of origin.

**19. 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 of MDB
1.	M/s Intra Health, 56-A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049)	<b>Manufacturer:</b> M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany  FSC Germany issued on 10-11-2016	Descocid-N (Disinfectant)  Class B  Shelf Life: 03 Years  Size: 1L, 5L, 10L Fee submitted: Rs.50,000/-	Surface disinfectant for medical devices Composition: 100 g contain: 13.2 g Benzalkonium chloride 6 g Didecyl dimethyl ammonium chloride 4.5 g Formic acid	<b>Deferred</b> for provision of following documents: Letter of Authorization (LOA) expired.  Provide valid LOA/agency agreement.  The LOA/Agency agreement shall be original, notarized from the

					<p>country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language. Clarification is required from manufacturer abroad as to which Authority/organization has issued this certificate and under what mandate?</p> <p>ISO 13485 and Full QA certificate is not notarized. Provide notarized certificates</p>
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					<p>Provide Essential Principles of Safety and Performance of applied product</p> <p>Stability studies not provided. Provide shelf life studies supporting claimed shelf life of 3 years</p> <p>Provide MRP for the applied device</p> <p>Provide details of manufacturing of the applied device</p> <p>Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3<sup>rd</sup> meeting.</p> <p>Provide label of the applied device</p>
2.	-do-	<b>Manufacturer:</b> M/s Antiseptica Dr. Hans-Joachim Molitor GmbH	Triacid-N (Disinfectant)  Class C	Aldehyde-free concentrate for the manual disinfection of	<b>Deferred</b> for provision of following documents:

		<p>Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany</p> <p>FSC Germany issued on 10-11-2016</p>	<p>Shelf Life: 03 Years</p> <p>Size: 1L, 5L</p> <p>Fee submitted: Rs.50,000/-</p>	<p>medical instruments</p> <p>Composition: 100 g contain: 18 g N-Dodecylpropa ne-1,3-diamine</p>	<p>Letter of Authorization (LOA) expired.</p> <p>Provide valid LOA/agency agreement.</p> <p>The LOA/Agency agreement shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language. Clarification is required from manufacturer abroad as to</p>
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					<p>which Authority/organization has issued this certificate and under what mandate?</p> <p>ISO 13485 and Full QA certificate is not notarized. Provide notarized certificates</p> <p>Product details provided in German language. Provide English translation of the document</p> <p>Provide Essential Principles of Safety and Performance of applied product</p> <p>Stability studies not provided. Provide shelf life studies supporting claimed shelf life of 3 years</p> <p>Provide MRP for the applied device</p> <p>Provide details of manufacturing of the</p>
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					<p>applied device</p> <p>Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3<sup>rd</sup> meeting.</p> <p>Provide label of the applied device</p>
3.	-do-	<p><b>Manufacturer:</b> M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich- Gauss-Strabe 7, 50259, Pulheim, Germany</p> <p>FSC Germany issued on 10-11- 2016</p>	<p>Biguacid-S (Disinfectant)</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Size: 1L, 5L, 10L</p> <p>Fee submitted: Rs.50,000/-</p>	<p>Aldehyde-free Surface disinfectant for medical devices</p> <p>Composition: 100 g contain: 17.5 g Didecyl dimeth yl ammonium chloride 4 g polyhexanide</p>	<p><b>Deferred</b> for provision of following documents: Letter of Authorization (LOA) expired. Provide valid LOA/agency agreement. The LOA/Agency agreement shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or</p>

					<p>category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language. Clarification is required from manufacturer abroad as to which Authority/organization has issued this certificate and under what mandate?</p> <p>ISO 13485 and Full QA certificate is not notarized. Provide notarized certificates</p> <p>Provide Essential Principles of Safety and Performance of applied product</p> <p>Stability studies not provided.</p>
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					<p>Provide shelf life studies supporting claimed shelf life of 5 years</p> <p>Provide MRP for the applied device</p> <p>Provide details of manufacturing of the applied device</p> <p>Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3<sup>rd</sup> meeting. Provide label of the applied device</p>
4.	-do-	<p><b>Manufacturer:</b> M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich- Gauss-Strabe 7, 50259, Pulheim, Germany</p> <p>FSC Germany issued on 10-11- 2016</p>	<p>Antiseptica Combi Instruments-N (Disinfectant)</p> <p>Class C</p> <p>Shelf Life: 03 Years</p> <p>Size: 1L, 5L</p> <p>Rs.50,000/-</p>	<p>For the manual disinfection of surgical instruments and laboratory equipment Composition: 100 g contain: 8 g Glutaraldehyd e 5.75 g Formacetale</p>	<p><b>Deferred</b> for provision of following documents: Letter of Authorization (LOA) expired. Provide valid LOA/agency agreement. The LOA/Agency agreement shall be original,</p>



					<p>notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language. Clarification is required from manufacturer abroad as to which Authority/organization has issued this certificate and under what mandate?</p> <p>ISO 13485 and Full QA certificate is not notarized. Provide</p>
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					<p>notarized certificates</p> <p>Provide Essential Principles of Safety and Performance of applied product</p> <p>Stability studies not provided. Provide shelf life studies supporting claimed shelf life of 3 years</p> <p>Provide MRP for the applied device</p> <p>Provide details of manufacturing of the applied device</p> <p>Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3<sup>rd</sup> meeting. Provide label of the applied device</p>
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5.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	<p>Flexicare Adult Breathing Circuit</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	<p>Single use Adult Breathing Circuit</p>	<p><b>Deferred</b> for provision of following documents: Letter of Authorization (LOA) is not NOTARIZE D. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied</p>
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					<p>product i.e Adult Breathing Circuit is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate</p> <p>Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how</p>
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					<p>can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
6.	-do-	<b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash,	Flexicare Paediatric Breathing Circuit  Codes & Sizes: Not CLEAR	Single use Paediatric Breathing Circuit	<b>Deferred</b> for provision of following documents: Letter of Authorization (LOA) is not

		<p>CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	<p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>		<p>NOTARIZE D. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e Paediatric Breathing Circuit is being manufactured in China site</p>
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					<p>or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate</p> <p>Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting</p>
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					<p>your claim with brochure, pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
7.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan)</p>	<p>Flexicare Oxygen and Aerosol Therapy Devices</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p>	Oxygen and Aerosol Therapy Devices	<p><b>Deferred</b> for provision of following documents: Multiple products cannot be applied on one application. Clearly state the one product that is required on</p>



		<p>Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	<p>Fee submitted: Rs.25,000/-</p>		<p>this application and then highlight the product codes of that product on Letter of Authorization , Free sale certificate and Declaration of Conformity. Provide brochure, pictures as well as all the labels of the codes required on this application under a single product name. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Letter of Authorization (LOA) is not NOTARIZE D. Provide the LOA/Agency</p>
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					<p>agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e Oxygen and Aerosol Therapy Devices is being manufactured in China site or UK site or both sites? and also who</p>
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					<p>is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
8.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan)</p>	<p>Flexicare Anaesthesia Components</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted:</p>	Anaesthesia Components	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZED. Provide the LOA/Agency agreement which shall be original,</p>

		<p>Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	Rs.25,000/-		<p>notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e Adult Breathing Circuit is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product?</p>
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					<p>Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate</p> <p>Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of</p>
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					<p>the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
9.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460,</p>	<p>Flexicare Anaesthesia Face Mask</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	Anaesthesia Face Mask	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZED. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity,</p>

		PR China.  FSC UK Issuance Date (15-02-2019)			names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusiv e authorization is given to importer.  Manufacturin g site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFAC TURER that the particular applied product i.e Anaesthesia Face Maskis being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturin g and QC tests of the applied device. If the
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					<p>product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate</p> <p>Single-use and reusable codes cannot be applied on one application. Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of the codes applied.</p>
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					<p>Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
10.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p>	<p>Flexicare Catheter Mount</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	Single-use Catheter Mount	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZE D. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of</p>

		FSC UK Issuance Date (15-02-2019)			<p>both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e Adult Breathing Circuit is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is</p>
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					<p>manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>ISO13485 (UK) expired. Provide valid certificate</p> <p>Clearly state whether the applied product codes are sterile or not-sterile? Sterile and non-sterile codes cannot be applied on one application. Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure,</p>
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					<p>pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
11.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli</p>	<p>Flexicare Endotracheal Tube</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	Sterile, single use endotracheal tube	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZED. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed</p>

		<p>Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>			<p>&amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e Endotracheal tube is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the</p>
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					<p>applied device</p> <p>Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Bougie shall</p>
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					<p>be applied n separate application</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
12.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	<p>Flexicare LarySeal laryngeal mask airways</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	LarySeal laryngeal mask airways	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZE D. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusiv e authorization is given to</p>

					<p>importer.</p> <p>Manufacturing site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e breathing filter is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also. If site is UK, then provide valid ISO13485 as the provided one is expired.</p>
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					<p>Single-use and reusable codes cannot be applied on one application. Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed</p>
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					shelf life.  Provide MRP for the applied device  Provide Instructions for use (IFU) for the applied device
13.	-do-	<p><b>Legal Manufacturer:</b> M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p><b>Manufacturing Site:</b> M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date (15-02-2019)</p>	<p>Flexicare Breathing Filters</p> <p>Codes &amp; Sizes: Not CLEAR</p> <p>Class B</p> <p>Shelf Life: 05 Years (NOT COMPLETE)</p> <p>Fee submitted: Rs.25,000/-</p>	Non-sterile, single-use breathing filters	<p>Deferred for provision of following documents: Letter of Authorization (LOA) is not NOTARIZED. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Manufacturin</p>

					<p>g site is not mentioned on form and is not clear from Free Sale Certificate. Clarification is required from MANUFACTURER that the particular applied product i.e breathing filter is being manufactured in China site or UK site or both sites? and also who is the legal manufacturer of the applied product? Then provide complete details of manufacturing and QC tests of the applied device. If the product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also</p> <p>Highlight the product codes required on this application on Letter of Authorization , Free sale</p>
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					<p>certificate and Declaration of Conformity. Justify how can the applied codes be grouped together on one application by supporting your claim with brochure, pictures as well as by providing all the labels of the codes applied. Clearly state the similarities and differences among the different codes applied and then provide stability studies for the applied codes supporting the claimed shelf life.</p> <p>Provide MRP for the applied device</p> <p>Provide Instructions for use (IFU) for the applied device</p>
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14.	<p>M/s Nisa Impex (Pvt) Ltd, Plot no. 13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA-II G.T. Road Islamabad.</p> <p>ELI-00064</p>	<p>Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus &amp; Instrument Co., Ltd. No. 46, 7<sup>th</sup> Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China.</p> <p>FSC INCOMPLETE</p>	<p>Nisa Medical Protective Face Mask</p> <p>Codes: FSC incomplete</p> <p>Class-A (firm applied as class B)</p> <p>Shelf life: 2 years (studies not provided)</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Used for filtering particles, blocking droplets, blood, bodily fluids and secretions in the air under the medical working environment.</p>	<p>Deferred for provision of following documents: The product is a class-A medical device. Submit Form-6A for the applied product including all the documents mentioned in the said form such as complete description of the applied product, complete documentation related to manufacturing and QC tests, standards applied and certificate of analysis, stability studies supporting claimed shelf life of 2 years, valid and notarized ISO13485, valid and notarized full QA certificate, Essential principles of safety and performance, Declaration of conformity etc</p> <p>Address of</p>
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					<p>importer mentioned on agency agreement is different than the address of the importer. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Original Free sale certificate is not found in the dossier and reference of its submission is also not provided. Submit original, valid, Free Sale certificate from the health</p>
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					<p>authorities of the country of origin duly attested by Embassy of Pakistan in that country for the applied product</p> <p>Provided label of the product provided is not readable. Provide readable labels of the codes required on this application along with description of the similarities and differences among the codes applied with pictures and brochure. These codes shall also be available on Free Sale Certificate</p> <p>Manufacturing site is not mentioned on form. Clearly state the name and address of the site where the masks are manufactured</p>
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15.	-do-	<p>Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus &amp; Instrument Co., Ltd. No. 46, 7<sup>th</sup> Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China.</p> <p>FSC NOT PROVIDED</p>	<p>Nisa Surgical Face Mask</p> <p>Codes: FSC not provided</p> <p>Class-A (firm applied as class B)</p> <p>Shelf life: 3 years (studies not provided)</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>For clinical medical personnel to wear in the process of traumatic operation to provide protection for the patients who are being treated and medical staff and prevent spread sores of blood, body fluids and splashes.</p>	<p>Deferred for provision of following documents: The product is a class-A medical device. Submit Form-6A with each page duly signed and stamped for the applied product including all the documents mentioned in the said form such as manufacturin g site, complete description of the applied product, complete documentatio n related to manufacturin g and QC tests, standards applied and certificate of analysis, stability studies supporting claimed shelf life of 3 years, valid and notarized ISO13485, valid and notarized full QA certificate, Essential principles of safety and</p>
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					<p>performance, Declaration of conformity etc.</p> <p>Address of importer mentioned on agency agreement is different than the address of the importer. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Free sale certificate not provided. Submit original, valid, Free Sale certificate from the health authorities of</p>
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					<p>the country of origin duly attested by Embassy of Pakistan in that country for the applied product</p> <p>Whether the product is available on free sale in reference countries provided in rule 67 of MDR, 2017? Provide original valid free sale certificate duly attested by Embassy of Pakistan.</p> <p>Provide readable labels of all the codes required on this application along with description of the similarities and differences among the codes applied with pictures and brochure. These codes shall also be available on Free Sale Certificate. Is the product sterile or not? If it is sterile then provide</p>
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					sterilization validation report of the site
16.	-do-	<p>Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus &amp; Instrument Co., Ltd. No. 46, 7<sup>th</sup> Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China.</p> <p>FSC INCOMPLETE</p>	<p>Nisa Medical Face Mask</p> <p>Codes: FSC incomplete</p> <p>Class-A (firm applied as class B)</p> <p>Shelf life: 3 years (studies not provided)</p> <p>Fee submitted: Rs. 5,000/-</p>	Suitable for health care in normal environment	<p>Deferred for provision of following documents: The product is a class-A medical device. Submit Form-6A with each page duly signed and stamped for the applied product including all the documents mentioned in the said form such as manufacturing site, complete description of the applied product, complete documentation related to manufacturing and QC tests, standards applied and certificate of analysis, stability studies supporting claimed shelf life of 3 years, valid and notarized ISO13485, valid and notarized full</p>

					<p>QA certificate, Essential principles of safety and performance, Declaration of conformity etc.</p> <p>Address of importer mentioned on agency agreement is different than the address of the importer. Provide the LOA/Agency agreement which shall be original, notarized from the country of origin, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive authorization is given to importer.</p> <p>Original Free sale certificate is not found in the dossier and reference</p>
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					<p>of its submission is also not provided. Submit original, valid, complete Free Sale certificate from the health authorities of the country of origin duly attested by Embassy of Pakistan in that country for the applied product</p> <p>Whether the product is available on free sale in reference countries provided in rule 67 of MDR, 2017? Provide original valid free sale certificate duly attested by Embassy of Pakistan.</p> <p>Provide readable labels of all the codes required on this application along with description of the similarities and differences</p>
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					among the codes applied with pictures and brochure. These codes shall also be available on Free Sale Certificate. Is the product sterile or not? If it is sterile then provide sterilization validation report of the site.
17.	M/s Eastern Medical Care (Pvt) Ltd, 7A Block N, Model Town Extension, Lahore  ELI-00130	Manufacturer: ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia  FSC Malaysia valid till 05-06-2020	ASAP Latex Powder Free 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, powder free, natural rubber latex examination glove	Deferred for provision of following documents: Form 6-A is not signed and stamped. Provide complete form 6-A with each page duly signed and stamped by the CEO  The brand name applied is ASAP and on Ireland Free Sale Certificate the name mentioned is Hevea. Clarification is needed from manufacturer ? Also if the applied product is the same product with same specification

					<p>that is available on Free Sale in Ireland?</p> <p>Provide valid, notarized Full QA or production QA certificate</p> <p>Provide EU Declaration of Conformity for the applied product</p>
18.	-do-	<p>Manufacturer: ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia</p> <p>FSC Malaysia valid till 05-06-2020</p>	<p>ASAP Latex Powdered Examination Gloves</p> <p>Size: Small, Medium, Large, Extra large, Extra Small, Extra extra large</p> <p>Class: A</p> <p>Shelf life: 3 years</p> <p>Fee submitted: Rs. 5,000/-</p>	Non-sterile, single use, powdered, natural rubber latex examination glove	<p>Deferred for provision of following documents: Form 6-A is not signed and stamped. Provide complete form 6-A with each page duly signed and stamped by the CEO</p> <p>The brand name applied is ASAP and on Ireland Free Sale Certificate the name mentioned is Hevea. Clarification is needed from manufacturer ? Also if the applied product is the</p>

					<p>same product with same specification that is available on Free Sale in Ireland?</p> <p>Provide valid, notarized Full QA or production QA certificate</p> <p>Provide EU Declaration of Conformity for the applied product</p>
19.	-do-	<p>Manufacturer: ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia</p> <p>FSC Malaysia valid till 05-06-2020</p>	<p>ASAP Lite Nitrile Powder free Examination Gloves</p> <p>Size: Small, Medium, Large, Extra large, Extra Small, Extra extra large</p> <p>Class: A</p> <p>Shelf life: 3 years</p> <p>Fee submitted: Rs. 5,000/-</p>	Non-sterile, single use, powdered, natural rubber latex examination glove	<p>Deferred for provision of following documents: Form 6-A is not signed and stamped. Provide complete form 6-A with each page duly signed and stamped by the CEO</p> <p>The product applied is ASAP Lite Nitrile Powder Free Examination Gloves where the documents provided are of Nitrile Powder free Examination</p>



					<p>Gloves. Clarification is required from manufacturer abroad that what is the exact different between Lite Nitrile Powder free Examination Gloves and simple Nitrile Powder free Examination Gloves? And provide the technical documents of Lite Nitrile Powder free Examination Gloves</p> <p>The product ASAP Lite Nitrile Powder Free Examination Gloves is not Free Sale Certificate of Ireland.</p> <p>The free sale certificate which is copy and not Embassy attested from country of origin i.e Malaysia is expired and the original Embassy attested free sale certificate of Malaysia is not found in</p>
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					<p>all 3 dossiers of gloves submitted. Provide Original, Valid and Embassy attested free sale certificate of Malaysia for all the three gloves namely ASAP Latex Powdered Examination Gloves, ASAP Latex Powder Free Examination Gloves and ASAP Lite Nitrile Powder free Examination Gloves.</p> <p>Provide valid, notarized Full QA or production QA certificate</p> <p>Provide EU Declaration of Conformity for the applied device</p>
20.	M/s Ghazali Brothers, Ground floor & Second Floor, Karimjee Building, North Napier Road, Karachi	<b>Manufacturer:</b> M/s Hefei Jingcheng Plastic Products Co. Ltd, 700 m east of Hong Tu Avenue and Dian Zhong	Care Face Mask  Class A  Shelf Life: Not provided  Fee submitted:	Not provided	Deferred for provision of following documents: Clarification is required from manufacturer if the product registered for

	(ELI-00240)	<p>Road Junction, Cuo Zhen Circular Economy Industrial Park, Hefei, China</p> <p>FSC UK Issuance Date (24-06-2019)</p>	Rs. 5,000/-		<p>use in the country of origin, i.e China? If yes then provide original, valid, Embassy attested Free Sale Certificate from country of origin for the applied product</p> <p>The MHRA free sale copy is not Embassy attested. Clearly state if the original embassy attested free sale certificate was submitted to DRAP or not. If yes then provide Embassy attested copy of the MHRA certificate</p> <p>Instruction for use for the applied product is not provided. Provide documents clearly stating the purpose of the applied product whether it is a medical mask or surgical mask</p>
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					<p>or for what is the intended use of the device, contraindications etc?</p> <p>Provide sample for the applied product</p> <p>Clearly state if the product is sterile or not? If it is sterile then provide sterilization validation report</p> <p>The masks do have shelf life so it is not justified that the product has no shelf life. Clearly state the shelf life of the product and provide stability studies from manufacturer abroad</p> <p>Provide the QC tests performed on the mask and clearly state the standards applied on the masks</p> <p>Provide essential principles of safety and performance</p>
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					<p>or essential checklist or essential requirements as per EU MDD 93/42/EEC</p> <p>Declaration of Conformity is not signed by responsible personnel. Provide signed and stamped Declaration of conformity on manufacturer letterhead</p> <p>Provide Undertaking required from the manufacturer that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel</p>
21.	M/s CCL Pharmaceuticals (Pvt) Ltd, 65 Industrial Estate, Kot Lakhpat, Lahore	<p>Manufacturer:</p> <p>M/s Ningbo Baige Bags Co., Ltd No. 2099 South Ningheng Road, Hengxi Town, Yinzhou District,</p>	<p>Assure Face Mask (Disposable Medical Face Mask)</p> <p>Class: A</p> <p>Shelf Life: 3</p>	Disposable Medical Face Mask	<p>Deferred for provision of following documents: Form 6-A is not stamped. Provide</p>

	ELI: 00562	Ningbo, Zhejiang, China	years Fee submitted: Rs. 5,000/-		<p>complete form 6-A with each page duly signed and stamped by the CEO or responsible official and provide Authority letter in case of authorized official</p> <p>Free sale certificate not provided. Submit original, valid, Free Sale certificate from the health authorities of the country of origin duly attested by Embassy of Pakistan in that country for the applied product having same brand name as that applied on this application</p> <p>Provide original Letter of Authorization or Agency agreement with manufacturer abroad, duly notarized in the country</p>
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					<p>of origin. Letter of Authorization or agreement shall be original, signed &amp; stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which authorization is given to importer</p> <p>Stability studies not provided. Provide complete stability studies supporting the shelf life claim of 3 years.</p> <p>Instruction for use for the applied product is not provided. Provide documents clearly stating the purpose of the applied product whether it is a medical mask or surgical mask</p>
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					<p>or for what is the intended use of the device, contraindications etc?</p> <p>Clearly state if the product is sterile or not? If it is sterile then provide sterilization validation report of site</p> <p>Provide the details of manufacturing and QC tests performed on the mask and clearly state the standards applied on the masks</p> <p>Provide essential principles of safety and performance or essential checklist or essential requirements</p> <p>Provide Undertaking from the manufacturer that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on</p>
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					<p>the letterhead signed and stamped by responsible personnel</p> <p>Provide MRP of the applied product</p> <p>Whether the product is available on free sale in reference countries provided in rule 67 of MDR, 2017? Provide original valid free sale certificate duly attested by Embassy of Pakistan.</p> <p>Provide ISO13485 certificate duly notarized in the country of origin</p> <p>Provide Full Quality Assurance certificate duly notarized in the country of origin</p> <p>Provide essential principles of safety and performance or essential checklist or essential requirements</p>
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					Provide Declaration on stamp paper as specified on Form 6-A
22.	M/s. United Healthcare Plot No. 330/B, 2nd Floor, DMCH, Bahadurabad, Karachi (ELI-00293)	<p><b>Manufacturer:</b> M/s. Jiangsu Jaysun Glove Co., Ltd No. 199 Jianling Avenue, SuQian economic and technological development zone, Suqian Jiangsu, China</p> <p>FSC China valid till 22-7-2021</p>	<p>Safety Examination Vinyl Gloves Size: XS, S, M, L, XL, XXL Class: A Shelf Life: 5 years Fee submitted: Rs. 5000/-</p>	<p>Vinyl gloves are used where high levels of durability and protection is not mandatory, vinyl makes a good multi-purpose glove for general use. Vinyl gloves are great for basic hand protection in a low infection environment. First synthetic alternative available offering an allergy free option to latex. They have advantages in resistant to acid, alkali, dirt and germs. Besides, they can be worn on either hand, and are easy to put on and take off.</p> <p>Non-sterile, single use, vinyl examination glove</p>	<p><b>Deferred</b> for provision of following documents: Powdered and powder-free gloves cannot be applied on one application. It is not clear that whether the applied product is powdered or powder-free and not mentioned on Free Sale Certificate also. Provide copy of registration letter of the product issued by Chinese FDA in order to establish if both the variants are available in the country of origin or provide Free Sale Certificate having both variants and clearly state that which type is required on this</p>

				<p><b>NTENDED USE</b></p> <p>It is intended to use in Medical Examination, hygiene inspection, chemical industry and pharmacy. These products provide users with protection when working in these areas</p>	<p>application? And provide the technical documents (detailed) i.e manufacturing and QC tests, stability studies of the type required</p> <p>Provide label and brochure of the applied device</p> <p>Provide valid, notarized Full QA or production QA certificate</p> <p>Is the product on Free Sale in any of the reference counties mentioned in rule 67 of MDR, 2017? Provide valid, original and Embassy attested Free Sale Certificate from any of reference regulatory authority</p> <p>Undertaking required from the manufacturer that same product with same specifications will be</p>
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					<p>supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel</p> <p>The essential principles provided does not bear product name so it cannot be established that this document is for the applied gloves. Clarify?</p>
23.	M/s Elate CC (Pvt) Ltd., Suite No. 1,2,3, Street No.3, Block No.3, Gulshan-e-Iqbal, Karachi (ELI-00294)	<p><b>Manufacturer:</b> M/s Siare Engineering International Group S.R.L. Via Giulio Pastore, 18 40053 Crespellano, Valsamoggia, Italy</p> <p>FSC Italy Issuance Date 31-12-2019</p>	<p>SIARE ICU Ventilators</p> <p>Class B</p> <p>Shelf Life: N/A</p> <p>Fee submitted:Rs.25,000/-</p>	Ventilator	<p>Deferred for provision of following documents: Ventilator is a class C medical device. Submit differential fee of Rs. 25,000/-</p> <p>Multiple models cannot be applied on application. Clearly state the model of ICU ventilator required on this application. That model shall be</p>

				<p>present on the Free Sale Certificate and provide the detailed technical documents i.e details of manufacturing and QC tests/performance report, Instruction-for-use having indications, contraindications etc, reference manual and label of the required model</p> <p>Provide copy of Establishment Licence to import medical device</p> <p>The Free Sale Certificate provided is not original, copy is provided. Provide original Embassy attested Free Sale Certificate</p> <p>Agency agreement is not original, copy is provided. Provide original Agency</p>
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					<p>agreement</p> <p>Copies of ISO 13485 and Full QA certificate are provided. Provide these certificates having original notarization</p> <p>Provide essential principles of safety and performance/essential checklist as per EU MDD 93/42/EEC for the required model of ventilator</p> <p>Provide Declaration of Conformity for the required model printed on the manufacturer letter head, filled and signed by the responsible person.</p> <p>Provide Declaration on stamp paper as specified on Form 7A</p> <p>Credentials not provided. Provide credentials of manufacturer</p>
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					abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3 <sup>rd</sup> meeting.  Provide MRP of the applied device
24.	-do-	<b>Manufacturer:</b> M/s Siare Engineering International Group S.R.L. Via Giulio Pastore, 18 40053 Crespellano, Valsamoggia, Italy  FSC Italy Issuance Date 31-12-2019	SIARE Anesthesia Machine  Class C  Shelf Life: N/A  Fee submitted: Rs.50,000/-	Anesthesia Machine	Deferred for provision of following documents: Multiple models cannot be applied on application. Clearly state the model of <b>Anesthesia Machine</b> required on this application. That model shall be present on the Free Sale Certificate and provide the detailed technical documents i.e details of manufacturing and QC tests/performance report, Instruction-for-use having indications, contraindications etc, reference manual and

					<p>label of the required model</p> <p>Provide copy of Establishment Licence to import medical device</p> <p>The Free Sale Certificate provided is not original, copy is provided. Provide original Embassy attested Free Sale Certificate</p> <p>Agency agreement is not original, copy is provided. Provide original Agency agreement</p> <p>Copies of ISO 13485 and Full QA certificate are provided. Provide these certificates having original notarization</p> <p>Provide essential principles of safety and performance/essential checklist as per EU MDD 93/42/EEC</p>
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					<p>for the required model of ventilator</p> <p>Provide Declaration of Conformity for the required model printed on the manufacturer letter head, filled and signed by the responsible person.</p> <p>Provide Declaration on stamp paper as specified on Form 7A</p> <p>Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3<sup>rd</sup> meeting.</p> <p>Provide MRP of the applied device</p>
25.	M/s Save on Health Care 101-B, Punjpeer Road Lalpul Mughalpura Lahore ELI: 00027.	<b>Legal Manufacturer:</b> Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai	<b>HITECARE</b> Laryngeal Mask Class-B Rs.25,000/-	Laryngeal Mask.	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of

	1150-(P)-DD(MD)	Peoples Republic of China.			country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
26.	-do-	<b>Legal Manufacturer:</b> Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China.	<b>HITECARE</b> Aerosol Mask Class-B Rs.25,000/-	The aerosol mask is used to administer medication to people in the form of a mist inhaled into the lungs.	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
27.	-do-	<b>Legal Manufacturer:</b> Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China  FSC: Germany  Date of Issue: 10.11.2019	<b>HITECARE</b>  (Oxygen Mask)  Class-B Shelf Life: 5 years  Rs.25,000/-	Oxygen Mask	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
28.	-do-	Hitec Medical Co., Ltd No, 703, Hengnan Rd Minhang District 201114 Shanghai China Authorized Representative: Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80	<b>HITECARE</b> Breathing Circuit Adult & Peads. Class-B Shelf Life: 05-years Rs.25,000/-	The disposable breathing circuit as of respiratory system offers a simple, convenient and efficient passage for clinic gas delivery, such as anesthetic	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-

		20537 Hamburg, Germany FSC: Germany Date of issue: 14 <sup>th</sup> November, 2019		gas, oxygen gas. It is used in include which offers cardio-respiratory system to general anesthesia patients and critical patients.	13485/ GMP certificate.
29.	-do-	<b>Legal Manufacturer:</b> Hitech Medical Co., Ltd No. 703, Hengnan Rd Minhang District 201114 Shanghai China FSC: China Date of Issue: 9 <sup>th</sup> Jan.2020	<b>HITECARE</b>  (HME filter viral & bacterial adult with connector) Class- B  Rs.25,000/-	HME filter viral & bacterial adult with connector	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
30.	-do-	<b>Legal Manufacturer:</b>  Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. FSC: Germany Date of Issue: 10.11.2019	<b>HITECARE</b>  (Reinforced Endotracheal Tube)  Class B  Shelf Life: 05 years  Rs.25,000/-	Reinforced Endotracheal Tube	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
31.	-do-	<b>Legal Manufacturer:</b> Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China  FSC: Germany	<b>HITECARE</b>  (Connecting tube with yankauer handle)  Class-B Shelf Life: 5 years  Rs.25,000/-	Connecting tube with yankauer handle	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency

		Date of Issue: 10.11.2019			agreement and ISO-13485/ GMP certificate.
32.	-do-	<b>Legal Manufacture:</b> M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu Street Conghua District Guangzhou City, China. FSC: China Valid Till: 07-06-2020	<b>DISPOSABLE SURGICAL</b> Gown & Isolation Gown. Class- A Shelf Life: 3 years  Rs.5,000/-	Disposable Surgical Gown & Isolation Gown	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement and ISO-13485/ GMP certificate.
33.	M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore  ELI: 00150.	Legal Manufacturer  M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany <b>Manufacturing Site:</b> Dragerwerk AG&Co. KgaA RevalstrBe 1 23560, Lubeck, Germany. FSC: Germany Date of issue: 15.10.19	<b>DRAGER DISPOSABLE</b> Anesthesia Masks COMFORT-STAT (Disposable Anaesthesia Masks) Codes & Sizes: As per FSC: Class-B Shelf Life: See annex-5  Rs.25,000/-	Disposable Anesthesia Masks	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, DoC, Labels, justification regarding different sizes and ISO-13485/ GMP certificate.
34.	M/s Endoaid Biomedica 185-C DHA EME Lahore  ELI: 00169.	Legal Manufacturer  Raysen (Tianjin) Health Care Product Co. Ltd No. 3 Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin China FSC: China Date of Issue: 15.05.2021	<b>RAYSEN</b> Face Mask  Disposable surgical Mask  Class: A Shelf Life: 5 years  Rs.5,000/-	Disposable Face mask	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, EPSPs, Labels,

					justification regarding different sizes and ISO-13485/ GMP certificate.
35.	-do-	Legal Manufacturer Mtaian Dalu Medical Instrument Ltd, West Part of Yitianmen street, HI- Tech Zone, Taian Shahdong China FSC: China Date of Issue: 2021.12.24	<b>FEE- BREATH</b> Disposable Nebulizers Class: A Shelf Life: 2 years  Rs.5,000/-	Disposable surgical Mask	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, EPSPs, Labels, justification regarding different sizes and ISO-13485/ GMP certificate.
36.	-do-	Legal Manufacturer  Raysen (Tianjin) Health Care Product Co. Ltd No. 3 Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin China  FSC: China Date of Issue: 29.06.2024	<b>RAYSEN</b> Surgical Gown  Disposable surgical Gown  Class: A Shelf Life: 5 years  Rs.5,000/-	Disposable Surgical Gown	<b>Deferred</b> for provision of details of mfg., justifiable stability study data, <b>original</b> and valid agency agreement & FSC of country of origin, EPSP and labels, complete description of the key functional elements, its formulation, its composition and its functionality.

37.	M/s Pak Punjab Cardex Medical Systems, Ground Floor, 210-J/2 Block, Johar Town, Lahore  ELI-00174	Legal Manufacturer:  M/s MHK Medikal Tekstill Sanayi ve Ticaret Limited Sirketi, Karkun Mah. Hidayet Card. No. 23/1 Oguzelii Gaziantep, Turkey.  FSC: Turkey	<b>MHK MEDIKAL</b> Disposable Sterile Surgical Gowns  (Disposable sterile Surgical Gowns)  Class-A  Shelf Life: 5 years  Rs.5,000/-	Disposable sterile Surgical Gowns	<b>Deferred</b> for provision of provide MRP, original and valid free sale certificate of country of origin duly notarized by the embassy and original agency agreement with all coded particulars duly notarized by the country of origin.
38.	M/s. Sadqain Healthcare Pvt Ltd. Rawalpindi. <u>ELI-00020.</u>	Legal Manufacturer: M/s. Intersurgical Limited. Crane House, Molly Millars Lane, wokingha, Berkshire, United Kingdom.	<b>FILTA MASK</b> with medium concentration oxygen mask and tubing.  Class: B	<b>FILTA MASK</b> with medium concentration oxygen mask and tubing	<b>Approved</b> subject to provision of original and valid free sale certificate of RRA (UK), original agency agreement and valid ISO-13485 has been expired and shelf life
39.	M/s. FM Health Care, 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road, <u>Karachi.</u>	Legal Manufacturer: M/s Well Lead Medical Co., Ltd., C-4 Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, China  FSC China Valid Till (09-02-2020)	<b>WELL LEAD</b> Laryngeal Mask Airways.  Class: B	Laryngeal Mask Airways	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, EPSPs, Labels, justification regarding different sizes and

					ISO-13485/ GMP certificate.
40.	-do-	Legal Manufacturer: M/s Well Lead Medical Co., Ltd., C-4 Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, China  FSC China Valid Till (09-02-2020)	<b>WELL LEAD</b> Oxygen Mask.  Class: B	Oxygen Mask	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, EPSPs, Labels, justification regarding different sizes and ISO-13485/ GMP certificate.
41.	-do-	Legal Manufacturer: M/s Well Lead Medical Co., Ltd., C-4 Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, China  FSC China Valid Till (09-02-2020)	<b>WELL LEAD</b> Disposable Air Cushion Face Mask.	Disposable Air Cushion Face Mask	Deferred for submission of justifiable stability study data, <b>original</b> and valid FSC of country of origin, <b>notarized</b> agency agreement, EPSPs, Labels, justification regarding different sizes and ISO-13485/ GMP certificate.
42.	M/s KM Enterprises, KM Mansion, 605-D Block MA Johor Town Lahore  ELI: 00054.	Legal Manufacturer:  M/s Biomax Ruber Industries SDN BHD. Malaysia+	<b>BIOMAX</b> (Latex Examination Gloves)  Class-A	Latex Examination Gloves	• <b>Deferred for submission of</b> technical details of mfg., QC, EPSP and

		60360388699  FSC: Malaysia  Valid till: 21.10.2020	Shelf Life: 5 years		labels (approved in country of origin), justifiable stability study data, original and valid agency agreement & FSC of country of origin. Clarify the classification of the product(s) applied i.e., given as Class-II in Health CANADA. Documentati on. So, you're advised to apply on the relevant form (i.e, Form- 7A) along with differential fee.
43.	-do-	Legal Manufacturer  M/s Changzhou Medical Appliance General Factory Co., Ltd China FSC: China Valid till: 06.06.2020	<b>AMD SURGICAL</b> Disposable Face Mask  (Face Mask)  Class-A  Shelf Life: N/A	Face Mask	<ul style="list-style-type: none"> <li>• <b>Deferred for submission</b> of technical details of mfg., QC, EPSP and labels (approved in country of origin), justifiable stability study data, original and valid agency agreement</li> </ul>



					& FSC of country of origin. Clarify the classification of the product(s) applied i.e., given as Class-II in Health CANADA. Documentation. So, you're advised to apply on the relevant form (i.e, Form-7A) along with differential fee.
44.	<b>M/s Waseem Brothers;</b> Plot No. B-45, Block 5, Gulshan-e-Iqbal, <u><b>Karachi.</b></u>	Legal Manufacturer: Top Gloves SDN. BHD, Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E Malaysia.	<b>LATEX Examination</b> Powdered Gloves. Class: A	<b>Examination</b> Powdered Gloves	<b>Deferred;</b> firm asked to provide ISO certificate, justifiable stability study data, technical details of EPSP, labels (approved in country of origin), QA Certificate and original and valid FSC of country of origin. In case of failure to comply, the case will be considered for rejection by MDB.

45.	-do-	Legal Manufacturer: Top Gloves SDN. BHD, Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E Malaysia.	<b>NITRILE Examination</b> Powdered Gloves.  Class: A	<b>NITRILE Examination</b> Powdered Gloves	<b>Deferred;</b> firm asked to provide ISO certificate, justifiable stability study data, technical details of EPSP, labels (approved in country of origin), QA Certificate and original and valid FSC of country of origin. In case of failure to comply, the case will be considered for rejection by MDB.
46.	M/s. Hakimsons (Pvt) Ltd., House A-58/B, SITE, Manghopir Road, <b><u>Karachi. (ELI-00396)</u></b>	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Development Zone, 315145, Ningbo, China	<b>OXYGEN MASK.</b> Class: B	<b>OXYGEN MASK</b>	<b>Approved</b> subject to provision of ISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life
47.	-do-	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Development Zone, 315145, Ningbo, China	<b>LARYNGEAL</b> Mask Airways. Class: B	Mask Airways	<b>Approved</b> subject to provision of ISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life

48.	-do-	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China	Nebulizer Mask. Class: B	Nebulizer Mask	<b>Approved</b> subject to provision of ISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life
49.	M/s. Medilink Trading and Maintenance Private Limited, 654-D, Canal view, <b><u>Lahore.</u></b>	Legal Manufacturer:  M/s. SUMBOW MEDICAL INSTRUMENTS CO., LTD.  Manufacturing Site: 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China  FSC: China Date of Issue: 07-05-2019	<b>MEDILINK CANADA</b> Surgical Disposable Face Mask. <b>Class: A</b>	Surgical Disposable Face Mask.	<b>Deferred</b> for provision of folowing documents:-  <ul style="list-style-type: none"> <li>• original and valid FSC of country of origin.</li> <li>• original agency agreement.</li> <li>• valid ISO-13485 certificate.</li> <li>• technical information for manufacturi ng, QC and EPSPs,</li> <li>• Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li> </ul>

50.	-do-	<p>Legal Manufacturer:</p> <p>M/s. SUMBOW MEDICAL INSTRUMENTS CO., LTD.</p> <p>Manufacturing Site: 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China</p> <p>FSC: China Date of Issue: 07-05-2019</p>	<p><b>MEDILINK CANADA</b> Surgical Nurse Cap. <b>Class: A</b></p>	Surgical Nurse Cap.	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• original and valid FSC of country of origin.</li> <li>• original agency agreement.</li> <li>• valid ISO-13485 certificate.</li> <li>• technical information for manufacturing, QC and EPSPs,</li> <li>• Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li> </ul>
51.	-do-	<p>Legal Manufacturer:</p> <p>M/s. SUMBOW MEDICAL INSTRUMENTS CO., LTD.</p> <p>Manufacturing Site: 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai</p>	<p><b>MEDILINK CANADA</b> Surgical disposable Shoe Cover. <b>Class: A</b></p>	Surgical disposable Shoe	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• original and valid FSC of country of origin.</li> <li>• original agency agreement.</li> <li>• valid ISO-13485</li> </ul>

		<p>Road, Yinzhou, Ningbo 315041, China</p> <p>FSC: China Date of Issue: 07-05-2019</p>			<p>certificate.</p> <ul style="list-style-type: none"> <li>• technical information for manufacturing, QC and EPSPs,</li> <li>• Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li> </ul>
52.	-do-	<p>Legal Manufacturer:</p> <p>M/s. SUMBOW MEDICAL INSTRUMENTS CO., LTD.</p> <p>Manufacturing Site: 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China</p> <p>FSC: China Date of Issue: 07-05-2019</p>	<p><b>MEDILINK CANADA</b> Surgical Nebulizer Mask. <b>Class: B</b></p>	Surgical Nebulizer Mask	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• original and valid FSC of country of origin.</li> <li>• original agency agreement.</li> <li>• valid ISO-13485 certificate.</li> <li>• technical information for manufacturing, QC and EPSPs,</li> <li>• Brand name includes CANADA while product is from CHINA.</li> </ul>

					Brand name gives impression of claim of the products from CANADA, which needs to be rectified.
53.	-do-	<p>Legal Manufacturer:</p> <p>M/s. SUMBOW MEDICAL INSTRUMENTS CO., LTD.</p> <p>Manufacturing Site: 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China</p> <p>FSC: China Date of Issue: 07-05-2019</p>	<p><b>MEDILINK CANADA</b> Surgical Oxygen Mask. <b>Class: B</b></p>	Surgical Oxygen Mask	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• original and valid FSC of country of origin.</li> <li>• original agency agreement.</li> <li>• valid ISO-13485 certificate.</li> <li>• technical information for manufacturing, QC and EPSPs,</li> <li>• Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li> </ul>
54.	M/s S.Ejazuddin & Co., PO Box 5629, Zia Plaza,	<p>Legal Manufacturer:</p> <p>Ansell Lank</p>	<p><b>ENCORE</b> Latex ortho-Surgical Gloves. (Powder-free)</p>	Latex ortho-Surgical Gloves. (Powder-free)	<p><b>Deferred</b> for provision of following documents:</p>

	Altaf Hussain Road, <b><u>Karachi.</u></b> <b><u>(ELI-00078)</u></b>	(Pvt) Ltd., Biyagma Export Processing Zone Biyagama-Srilanka  (FSC Srilanka 22-06-2011)	<b>Class B</b>		<ul style="list-style-type: none"> <li>• complete technical info. Of mfg.</li> <li>• QC details,</li> <li>• valid Full QA Certificate of manufacturer.</li> <li>• original &amp; valid agency agreement.</li> <li>• FSC of SRA with the instant product, with all coded particulars</li> </ul>
55.	<b>M/s Imtiaz Brothers,</b> Suits#7B, 2 <sup>nd</sup> Floor, Abrar Business Center, 25-Main Wahdat Road, <b><u>Lahore.</u></b> <b><u>ELI: 00133.</u></b>	Legal Manufacturer  M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China  Valid Till: 07-06-2020	<b>STERILE SURGICAL</b> Face Mask. Class-A.	<b>STERILE SURGICAL</b> Face Mask	<b>Deferred</b> for provision of original and valid FSC of country of origin, original agency agreement, and justifiable stability study data for the claimed shelf-life.
56.	<b>-do-</b>	Legal Manufacturer  M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu Street Conghua District	<b>DISPOSABLE SURGICAL</b> Gown & Isolation Gown. Class- A.	Disposable Surgical Gown & Isolation Gown	<b>Deferred for</b> provision of original and valid FSC of country of origin, original agency agreement, and

		Guangzhou City Peoples Republic of China  FSC: China  Valid Till: 07-06- 2020			justifiable stability study data for the claimed shelf-life.
57.	Meher Traders, Office A21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi (ELI-00128) 2813	<b>Legal Manufacture</b> M/s Anhui Anyu Latex Products Co., Ltd., No.95 Yuhe Road, 233010 Bengbu, Anhui, China	Wellmed Sterile Surgical Gloves Powdered Class: B	Sterile Surgical Gloves Powdered	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO- 13485 certificate and shelf life
58.	-do-	<b>Legal Manufacture</b> M/s Ningbo Great Mountain Medical Instruments Co. Ltd., E-Building 1606 Room, 655 Xueshi Road, Yinzhou District, Ningbo, China	Wellmed Oxygen Mask Class: B	Oxygen Mask	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO- 13485 certificate and shelf life
59.	-do-	<b>Legal Manufacture</b> M/s Ningbo Great Mountain Medical Instruments Co. Ltd., E-Building 1606 Room, 655 Xueshi Road, Yinzhou District, Ningbo, China	Wellmed Nebulizer Mask Class: B	Nebulizer Mask	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO- 13485 certificate and shelf life



60.	-do-	<b>Legal Manufacture</b> M/s Ningbo Great Mountain Medical Instruments Co. Ltd., E-Building 1606 Room, 655 Xueshi Road, Yinzhou District, Ningbo, China	Wellmed Nasal Oxygen Cannula Class: B	Nasal Oxygen Cannula	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO-13485 certificate.
61.	-do-	<b>Legal Manufacture</b> M/s Anhui Anyu Latex Products Co., Ltd., No.95 Yuhe Road, 233010 Bengbu, Anhui, China	Wellmed Sterile Surgical Gloves Powdered Free Class: B	Sterile Surgical Gloves Powdered Free	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO-13485 certificate and shelf life
62.	-do-	<b>Legal Manufacture</b> M/s Ningbo Great Mountain Medical Instruments Co. Ltd., E-Building 1606 Room, 655 Xueshi Road, Yinzhou District, Ningbo, China	Wellmed HMEF (Heat & Moisture Exchange Filter) Class: B	HMEF (Heat & Moisture Exchange Filter)	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued by CCI, China) and valid ISO-13485 certificate and shelf life
63.	-do-	<b>Legal Manufacture</b> M/s Ningbo Great Mountain Medical Instruments Co. Ltd., E-Building 1606 Room, 655 Xueshi Road,	Wellmed Disposable Anesthetic Breathing Circuit Class: B	Disposable Anesthetic Breathing Circuit	<b>Approved</b> subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued

		Yinzhou District, Ningbo, China			by CCI, (China) and valid ISO- 13485 certificate and shelf life.
64.	M/s Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	Legal Manufacturer: M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018, USA  Manufacturing Site M/s Tecan Schweiz AG 103 Seestrasse Maennedorf Zuerich, Zurich, 8708 Switzerland.  FSC USFDA Valid Till (30-01-2021)	<b>M24sp Instrument.</b> (PCR Analyzer.) (IVD-Machine)  Class: C	(PCR Analyzer.) (IVD- Machine)	<b>i. Deferred for provision of follwoings:</b> In accordanc e with 5(vi) of form-7A provide the ISO- 13485/ GMP certificate; <b>ii. Provide service life protocols &amp; studies.</b> Grouping and components of the subject product (that are grouped together) for registration in the instant application are not clear. Furthermore, the product is used for the measurement of highly exponential phase of RNAs during polymerase chain reaction (PCR), So <b>product should be classified in higher risk class, i.e., class-C and you're</b>

					<b>advised to apply accordingly.</b>
65.	-do-	<p>Legal Manufacturer: M/s Diatron MI Plc. H-1097, Budapest, Tablas u 39. Hungary.</p> <p>FSC Hungary Issuance Date (22-11-2019)</p>	<p><b>ALERE H-380</b> Hemo-analyzer. (IVD-Machine).  Class: B</p>	Hemo-analyzer. (IVD-Machine).	<p><b>Approved subject to;</b> provision of ISO-13485/ GMP certificate, Provide service life protocols &amp; studies, and Provide the application on Form-7A with all coded particulars and differential fee as per decision of MDB.</p>
66.	M/s. Cardiac Care, 848-C Shadman-I, <u>Lahore. ELI-00070.</u>	<p><b>Legal manufacturer:</b> M/s. HSINER Co., Ltd 312 Jhongshan Rd, Shengang Dist, Taichung 429 Taiwan. FSC: 179aiwan Date of issue: 14.11.2019.</p>	<p><b>CPAP/VPAP</b> Oxygen Mask and Accessories.  Class: B Shelf life: 03-years.</p>	Oxygen Mask	<p><b>The Board considering the Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs rejected the request of M/s Cardiac Care, Lahore for registration of their product namely CPAP/VPAP Oxygen Mask and Accessories</b></p>

67.	-do-	<b>Legal manufacturer:</b> M/s. HSINER Co., Ltd 312 Jhongshan Rd, Shengang Dist, Taichung 429 Taiwan FSC: 180aiwan Date of issue: 14.11.2019.	Oxygen Mask and Accessories Oxygen Mask and Accessories 35171-35173, 35175,35178,35113 Class: B Shelf life 3 years.	Oxygen Mask	<b>The Board considering the Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs rejected the request of M/s Cardiac Care, Lahore for registration of their product namely Oxygen Mask and Accessories</b>
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**20. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision of MDB
1.	3N-Lifemed Pharmaceuticals, 45 SB Abdullah Colony, Sargodha (ELM-)	Lifemed Acetic Acid 30% (3NLAA30) Shelf Life: 3 Years Class C Rs. 20,000/-	Decalcificator/disinfectant for Haemodialysis Machine	<b>Approved.</b>
2.	-do-	Lifemed Citric Acid 30% (3NLCA30)	Decalcificator/disinfectant for Haemodialysis Machine	<b>Approved.</b>

		Shelf Life: 3 Years Class C Rs. 20,000/-		
3.	-do-	Lifemed Citro HD (3NLCPSV) Shelf Life: 3 Years Class C Rs. 20,000/-	Decalcificator/disinfectant for Haemodialysis Machine	<b>Approved.</b>
4.	-do-	Lifemed Citric Acid 50% (3NLCA50) Shelf Life: 3 Years Class C Rs. 20,000/-	Decalcificator/disinfectant for Haemodialysis Machine	<b>Approved.</b>

## 21. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision of MDB
1.	Uniferoz (Pvt) Ltd, 32/8 & 33/2, Sector 15, Korangi Industrial Area, Karachi (ELM-0011)	Dermapore Transparent Surgical Tape. Transparent Polyethylene (PE) Type.  Class A  Shelf Life: 04 Years  Rs. 5,000/-  Sizes as per form Pack	Polyethylene backing with hypoallergic adhesive.	<b>Deferred</b> for product specific inspection.

		Sizes. 12mm x4.5m 25mm x 4.5m 50 mm x 4.5m 75 mm x 4.5m 100 mm x 4.5m		
2.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014)	Soft Med Mask (Surgical Mask KN-95)  Class A  Shelf Life: 03 Years  Rs.5000/-	Surgical Mask KN-95	<b>Deferred</b> for inspection to verify the mask manufacturing facility.
3.	-do-	Soft Med Mask (Surgical Face Mask 3 Ply)  Class A  Shelf Life: 03 Years  Rs.5000/-	Surgical Face Mask 3 Ply	<b>Deferred</b> for inspection to verify the mask manufacturing facility.

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

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision of MDB
1.	M/s Cotton Craft (Pvt) Ltd No. 407-408, Sunder Industrial Estate, Raiwand, Lahore.	Parachlor Tulle Grasx  Contains: Chlorhexidine acetate BP....0.5%  5cm x 5cm 10cm x 10cm 15cm x 20cm 15cm X 150cm	The Product validation by following the ISO 13485 standard. Gamma irradiation is used for product sterility. The packaging, sterility and quality of the final product will be tested.	<b>Deferred</b> for inspection to verify the testing facility for Chlorhexidine acetate.

		Class: C Shelf Life: 03 Years  Rs. 10,000/-		
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**23. REGISTRATION OF RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision of MDB
1.	Cotton Craft (Pvt) Ltd., 12-KM, Multan Road, Canal View Society, Lahore (ELM-0015)	Elastocraft (Cotton Crepe Bandage BP)  Class A  Shelf Life: 05 Years  Rs.5,000/-  Renewal Sizes as existing registration	Cotton Crepe Used to reduce swelling, relieve pain etc.	<b>Approved.</b>

**24. DEFERRED CASE OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.**

Following application for registration of Medical Devices for manufacture was placed before the MDB in its 24<sup>th</sup> meetings and deferred for provision of document. Now the firm has submitted the documents

S.#	Name of Firm (s)/manufacturer	Name of Medical Device	Brief Description	Decision of MDB
1.	M/s Renacon Pharma Ltd. Lahore.	Renapulv-N Hemodialysis concentrate  Hemodialysis Concentrate Shelf Life: 2 years	Used In Hemodialysis Of Kidney Failure Patients	<b>Approved.</b>

		Class: C Fee Submitted Rs 20,000		
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**25. RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT  
(FORM-7A).**

Sr: #.	Name of products	Manufacture name	Name of Medical Devices & Size	Decision of MDB
01.	M/s Grace Pharmaceuticals office # 102, First floor, The plaza, Block-9 Clifton, Karachi.	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b> Auto Disable Syringe.  Class B Sizes as per FSC 0.5ml, 1ml, 2ml, 5ml	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
02	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b> Scalp Vein Set Class B  Sizes as per FSC 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm 0.9mm, 1.2mm	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
03.	-do-	<b>Legal Manufacturer:</b>  JianxiHongda Medical Equipment Group Ltd.  No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China.  (FSC China Valid Till 26-11-2021)	<b>ALPHA</b> IV Cannula Class B Sizes as per FSC 0.6x16mm (26Gx0.63IN), 0.6x19mm (26Gx0.75IN) 0.7x19mm (24Gx0.75IN) 0.9x19mm (22Gx0.75IN) 0.9x25mm (22Gx1.00IN) 1.0x32mm (20Gx1.25IN) 1.0x25mm (20Gx1.00IN) 1.0x30mm (20Gx1.16IN) 1.1x48mm (20Gx1.88IN) 1.3x30mm (18Gx1.16IN) 1.3x48mm (18Gx1.88IN) 1.6x55mm	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.

			(16Gx2.17IN) 2.0x55mm (14Gx2.17IN) Model: Two-way Connector Type, (Pen type or with injection port) Y-connector type size : 0.6x16mm (26Gx0.63IN)	
04.	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b>  Blood Transfusion Set  Class B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
05.	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b>  Infusion Set  Class B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
06.	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b>  Disposable Insulin Syringe  Class B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
07.	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b>  Disposable Syringes  (3ml, 5ml, 10ml and 20ml)  Class B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
08.	-do-	<b>Legal Manufacturer:</b>  JianxiHongda Medical Equipment Group Ltd.	<b>ALPHA</b>  Brutte Chamber 100 ml	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of

		No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	Class B Codes & Sizes as per FSC.	MDR, 2017.
09.	-do-	<b>Legal Manufacturer:</b> JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	<b>ALPHA</b> Disposable Syringes (50ml)  Class B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.

## 26. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

Sr.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Decision of MDB
1.	M/s Grace Pharmaceuticals office # 103,5 <sup>th</sup> floor, Plot No 42 C/2, Lane # 8 Bukhari Commercial DHA Phase-6, Karachi.	Legal Manufacturer Address: 39 SouothShengli Road Jianxian Country, Jiangxi Province, China FSC: China (Copy)	Alpha Suction Catheter Class-B Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, <b>original</b> and valid agency agreement & FSC of country of origin as per MDR, 2017.
2.	-do-	Legal Manufacturer Address: 39 SouothShengli Road Jianxian Country, Jiangxi Province, China FSC: China	Alpha Endocrocheal Tyne Class-B. Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, <b>original</b> and valid agency agreement & FSC of country of origin as per MDR, 2017.
3.	-do-	Legal Manufacturer Address: 39 SouothShengli Road Jianxian Country, Jiangxi Province, China FSC: China	Alpha Stomach Tube Class-B. Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, <b>original</b> and valid agency agreement & FSC of country of origin as per MDR, 2017.
4.	-do-	Legal Manufacturer Address: 39 SouothShengli Road Jianxian	Alpha Foley Catheter Class-B. Codes & Sizes	<b>Approved</b> subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, <b>original</b> and

		Country, Jiangxi Province, China FSC: China	as per FSC.	valid agency agreement & FSC of country of origin as per MDR, 2017.
5.	-do-	Legal Manufacturer Address: 39 SouothShengli Road Jianxian Country, Jiangxi Province, China FSC: China	Alpha Blood Collection Needle Class-B. Codes & Sizes as per FSC.	<b>Approved</b> subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, <b>original</b> and valid agency agreement & FSC of country of origin as per MDR, 2017.

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