$\frac{\text{DECISIONS OF THE 26}^{\text{TH}}\text{MEETING OF THE MEDICAL DEVICE BOARD (MDB)}}{\text{HELD ON 06-01-2021}}$

1. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.</u>

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.	Approved.
2.	M/s Health Mark Scientific & Co, 302, Plot 99, Sharmeen Corner, Block 3, B.M.C.H.S., Bahadurabad, Karachi. Godown: Same as Above.	Muhammad Waleed	No	Approved 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. Godown Address: Al-Madina Arcade, Shope No. 5, Clifton, Karachi.	Aamir Iqbal	Yes	Approved.
4.	M/s Nawan Laboratory (Pvt) Ltd. Plot No. 136-138, Sector 15, Korangi Industrial Area, Karachi. Godown: Same as Above.	Mr. Ehsan Naseer Awan (CEO)	Yes	Approved for room temperature medical devices with cold chain facility.
5.	M/s Orient Traders International, Commercial-10,	Mr. Khalid Iqbal Mr. Shabana Musarrat	No.	Approved.

	Block A, Kazimabad, Model Colony, Karachi. Godown-1: CM Block-A, Kazimabad Model Colony, Karachi. Godown-2: CM-18 Block-A, Kazimabad Model Colony, Karachi.			
6.	M/s Hakimsons (Impex) Pvt. Ltd, Hakimsons Building, 19 West Wharf Road, Karachi. Godown: Same as Above.	Mr. Zulfiqar Ali Hakim (CEO)	No.	Approved.
7.	M/s Z.U International, 32-33 Muslim masjid, O/s Lahori Gate, Lahore. Godown: Same as Above	Mr. Usman Bashir Mr. Zia Saeed	No	Approved.
8.	M/s MHK Enterprises, Jalal Heights, Flat No. 201, Plot No. 4, St.10D, & 10P, Al- Hilal, C.H.S, Gulshan-e-Iqbal, Karachi. Godown Address: N-118, Bloc-2, P.R.C.H.S., Karachi.	Mrs. Ghazala Rashid	Yes.	Approved for room temperature medical devices with cold chain facility.
9.	M/s Aqib Trading Company (Pvt) Ltd, Main G.T Road, Adamzai, AkoraKhattak, Nowshera. Godown Address: 1st Floor, M/s Unisa Pharmaceutical Industries Ltd., Main G.T.oad, Adamzai, Akora Khattak,	Mr. Aqib Ismail Mrs. Samreen Aqib	No.	Approved alongwith storage facility at 1 st 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. Godown: Shop No. 4,5,6,7, My Mall apartments Unit No. 09, Latifabad, Hyderabad.	Mr.Sharique Khalid Farooqui	No	Approved. Qualification of Qualified Person is not as per MDR, 2017
11.	M/s Tameer International, 112- Aziz Shaheed road, Cantt, Madina Town, Sialkot.	Shahida Parveen	No.	Approved 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.	Approved for storage of room temperature medical devices.
13.	M.s Nolivaa Pharmacon, Suit No. 312, 3 rd floor, Anum Blessing Block-7/8, K.C.H.S.U., Main Shahrah-e-Faisal, Karachi. Godown: Same as Above	Syed Naeem Jawed	No	Approved 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	Approved for storage of room temperature medical devices.
15.	M/s Orbit Diagnostics, Apt No. 403, 4 th Floor, Plaza No. 55, Phase 4, Bahria Town, Islamabad.	Mr. Wajahat Qamar Butt Mr. Usman Javaid	Yes	Approvedfor storage of room temperature medical devices and devices requiring cold chain.
	Above			DSL not Provided
16.	M/s AGBL Pakistan	Mr. Yasir Saleem	No.	Approved for

17.	(Pvt) Ltd., Office.508, 5th Floor, Parsa Topwer, Main Shahra- e-Faisal, Karachi. M/s Hakimi Medtech, Room No.4, Jason Centre, BC 8, Block- 9, Clifton, Karachi.	Fady Al Assaly (CEO) Mr. Abbas Ali Sana Fawad	No.	storage of room temperature and temperature sensitive medical devices. Approvedfor 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.	Approvedfor 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. Godown Address: F-08, First Floor, Glass Tower, Adjacent PSO Office, Clifton, Karachi.	Mr.Rohit Kumar	No.	Approvedfor 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	Approvedfor storage of room temperature medical devices.
21.	M/s Noori Enterprises, D-145, Block-5, F.B. Area, Karachi.		No	Approvedfor 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.	Rejected 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. Godown: 513-5 Sector 6/A, KI.A. Mhran Town, Korangi, Karachi.	Mr. Muhammad Arbab Idrees Tuba Ahsan	No.	Approved 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. Godown Addres: Same as above.	Mr. Irfan Rafique Mr. Zain Irfan Ms. Mona Irfan Mr. Fraz Irfan	No	Approved for storage of room temperature medical devices subject to hiring of technical person.

2. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.</u>

<u>2.1.</u>

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.

<u>2.2.</u>

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-

703888) 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. <u>APPROVAL OF SITES FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.</u>

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, 1st 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:-

Existing Name and Address of Establishment			Prop	oposed Name and Address of Establishment 's Premier Sales (Private) Limited, Head					
M/s	Premier	Agencies,	60-Muslimabad,	M/s	Premier	Sales	(Private)	Limited,	Head

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

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

Existing Technical Person	Proposed Technical Person
Ms. Asiya Amjad, House No.89, Alfalah Society	Mr. Maaz Uddin Ahmed Siddiqui, House No.B-
Malir Halt, Malir, Karachi.	53, Sector 18-A, KUEHS,, KDA Scheme 33
CNIC # 42101-8842238-6	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:-

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

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:-

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

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

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

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:-

Existing Technical Person	Proposed Technical Person
Mr. Muhammad Shahbaz Hussain, House	Sabayyel Hassan, Gujranwala Road, Street No.2,
No.195/6, Sharqi Colony, Janubi Block, Vehari.	Mohallah Qazi Pura, Hafizabad.
CNIC # 36603-1450277-7	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:-

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

4.5.

M/s Imtiaz Brothers, Suit No.7-B, 2nd 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:-

Existing Technical Person	Proposed Technical Person
Ms. Nadia Tanveer, House No.539-B, Gulshan-	Ms. Syeda Urooj Shah, House No.12-E, Street
e-Ravi, Lahore	No.4, Scheme No.01, Rachna Town, Ferozwala,
	District Sheikhupura.
CNIC # 35202-3583192-4	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:-

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

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:-

Existing Address	Proposed Address
102, 1 st Floor, Block-9, Clifton, Karachi.	Office No.305, 5 th 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:-

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

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: -

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

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

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

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

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

- 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.
- 7. Ms. Seema Khan, House No.SU-465, Askari V, Malir, Karachi. CNIC: 42501-2987789-0.
- 5. Mr. Ehsan Ali Malik, 41A, South Central Avenue, Phase II, DHA, Karachi. CNIC:42301-7554100-1.
- 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.

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:-

Existing name (s) of Proprietors/Dirctors.	Proposed name (s) of Proprietors/Directors.
1. Mr. Rashid Abdullah, Houe No.5, Block 7/4,	1. Mufti Zia Ul Islam, Flat No.C-5, KDA
DMCHS, Tipu Sultan Road, Karachi.	Safari Terrace, FL-17, zand 26, Block 11,
CNIC:42201-1132967-1.	Gulshan-e-Iqbal, Karachi. CNIC:42000-
2. Mr. Adnan Asdar Ali, House No.B-40/1, Block	0467228-3
3, Clifton, Karachi. CNIC:42301-1091664-3.	2. Mr. Rashid Abdullah, Houe No.6, Street
3. Mr. Syed Nadeem Ahmad, House No.86/1, St.	No.9, Falcon Complex, AFOHS, Off
24, Khayaban-e-Sehar, Phase 6, DHA,	Shaheed-e-Millat Road, Karachi.
Karachi. CNIC:42301-0869989-9.	CNIC:42201-1132967-1.
4. Mr. Zubair Razzak Palwala, House No.27-	3. Mr. Shahid Abdullah, Houe No.5, Street
B/11, Street No. Q, Phase 6, DHA, Karachi.	No.9, Falcon Complex, Shaheed-e-Millat
CNIC:42201-5080780-3.	Road, Karachi. CNIC:42201-4240175-5.
5. Mr. Ayaz Abdullah, House No.210, St. No.2,	4. Mr. Syed Nadeem Ahmad, House No. B6/1,
AFOHS, Falcon Complex, Main Shahrah-e-	St. 24, Khayaban-e-Sehar, Phase 6, DHA,
Faisal, Karachi. CNIC:42201-8726172-1.	Karachi. CNIC:42301-0869989-9.
6. Ms. Shaista Khaliq, House No.54/1, St No.B-	5. Mr. Zubair Razzak Palwala, House No.20,
6 th , Phase 5, DHA, Karachi. CNIC:42301-	Street N, Phase 4, DHA, Karachi.
8797867-2.	CNIC:42201-5080780-3.
	6. Mr. Shuja Malik, House No.33, Street
	No.20, Khayaban-e-Tanzeem, DHA-5,
	Karachi. CNIC:42301-1600531-9.
	7. Mst. Ameena Saiyid, House No.43-7, H
	Block-7, PECHS, Karachi. CNIC:42201-
	0421840-4.
Existing Address	Proposed Address
1 st Floor, NICL Building, Abbasi Shaheed Rpad,	Section A, 2 nd Floor, One IBL Centre, Plot
Karachi.	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:-

Previous Address of Establishment	New Approved Address of Establishment
1 st Floor, NICL Building, Abbasi Shaheed	Section A, 2 nd Floor, One IBL Centre, Plot
Rpad, Karachi.	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.
1. Mr. Rashid Abdullah, Houe No.5,	1. Mufti Zia Ul Islam, Flat No.C-5, KDA
Block 7/4, DMCHS, Tipu Sultan	Safari Terrace, FL-17, zand 26, Block 11,
Road, Karachi. CNIC:42201-	Gulshan-e-Iqbal, Karachi. CNIC:42000-
1132967-1.	0467228-3
2. Mr. Adnan Asdar Ali, House No.B-	2. Mr. Rashid Abdullah, Houe No.6, Street
40/1, Block 3, Clifton, Karachi.	No.9, Falcon Complex, AFOHS, Off
CNIC:42301-1091664-3.	Shaheed-e-Millat Road, Karachi.
3. Mr. Syed Nadeem Ahmad, House	CNIC:42201-1132967-1.
No.86/1, St. 24, Khayaban-e-Sehar,	3. Mr. Shahid Abdullah, Houe No.5, Street
Phase 6, DHA, Karachi. CNIC:42301-	No.9, Falcon Complex, Shaheed-e-Millat
0869989-9.	Road, Karachi. CNIC:42201-4240175-5.
4. Mr. Zubair Razzak Palwala, House	4. Mr. Syed Nadeem Ahmad, House No.
No.27-B/11, Street No. Q, Phase 6,	B6/1, St. 24, Khayaban-e-Sehar, Phase 6,
DHA, Karachi. CNIC:42201-	DHA, Karachi. CNIC:42301-0869989-9.
5080780-3.	5. Mr. Zubair Razzak Palwala, House No.20,
5. Mr. Ayaz Abdullah, House No.210,	Street N, Phase 4, DHA, Karachi.
St. No.2, AFOHS, Falcon Complex,	CNIC:42201-5080780-3.
Main Shahrah-e-Faisal, Karachi.	6. Mr. Shuja Malik, House No.33, Street
CNIC:42201-8726172-1.	No.20, Khayaban-e-Tanzeem, DHA-5,
6. Ms. Shaista Khaliq, House No.54/1, St	
No.B-6 th , Phase 5, DHA, Karachi.	7. Mst. Ameena Saiyid, House No.43-7, H
CNIC:42301-8797867-2.	Block-7, PECHS, Karachi. CNIC:42201-
	0421840-4.

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:-

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

Mr. Aamir Hussain Shirazai, House # 3, Zaman	Mr. Aamir Hussain Shirazai, House # 3,
Park, Lahore. CNIC: 35202-3854859-7	Zaman Park, Lahore. CNIC: 35202-
	3854859-7
Mr. Saqib Hussain Shirazi, House No.12, Street	
5, Khayaban-e-Bukhari, Phase VI, DHA,	Mr. Saqib Hussain Shirazi, House No.12,
Karachi. CNIC: 42000-0509678-5	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-	Mr. Ali Hussain Shirazi, 2-Khayaban-e-
0972346-1	Ghazi Phase-V, DHA, Karachi. CNIC:
	42301-0972346-1
Mr. Farooq Saleem, 111/2, Street 16 Khayaban-	
e-Muslim DHA 6, Karachi. CNIC:42301-	Mr. Farooq Saleem, 141/2, Street 16
3842441-9.	Khayaban-e-Muslim Phase-6, DHA
	Karachi. CNIC:42301-3842441-9.
Mr. Khaleeq-ur-Rehman Khan Yousufi, House	
No.150/1, 35 th Street Khayaban-e-Muslim	Mr. Iftikhar Hussain Shirazi, 2-Khayaban-e-
D.H.A VI, Karachi.	Ghazi Phase-V, DHA, Karachi. CNIC:
, ,	42301-0948515-3.
	12001 07 10010 01

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

Previous Address of the Establishment	New Approved Address of the Establishment
8 th Floor, Adamjee House, I.I. Chundrigarh	No.114-CAl-Murtaza Commercial Lane 3,
Road, Karachi.	Khayaban-e-Iqbal, Phase 8, DHA, Karachi.
Existing Name of Proprietors/Directors	Proposed Name of Proprietors/Directors
Mr. Yusuf Hussain Shirazi,2-Khayaban-e-	Mr. Bashir Makki, House No.62/1, St. No.21,
Ghazi Phase-V, DHA, Karachi.	Khayaban-e-Baadban, Phase-5, DHA, Karachi.
42301-3842441-9	CNIC: 42301-0961322-3
M. A Harris Gliveri H. 2. 7	M. A U Chianni H. 2. 7
Mr. Aamir Hussain Shirazai, House # 3, Zaman	Mr. Aamir Hussain Shirazai, House # 3, Zaman
Park, Lahore. CNIC: 35202-3854859-7	Park, Lahore. CNIC: 35202-3854859-7
Mr. Saqib Hussain Shirazi, House No.12, Street	Mr. Saqib Hussain Shirazi, House No.12, Street 5,
5, Khayaban-e-Bukhari, Phase VI, DHA,	Khayaban-e-Bukhari, Phase VI, DHA, Karachi.
Karachi, CNIC: 42000-0509678-5	CNIC: 42000-0509678-5
Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi	Mr. Ali Hussain Shirazi, 2-Khayaban-e-Ghazi
Phase-V, DHA, Karachi. CNIC: 42301-	Phase-V, DHA, Karachi. CNIC: 42301-0972346-
0972346-1	1
M F G1 111/2 G 116 W 1	M F C1 141/2 Ct 116/21 1
Mr. Farooq Saleem, 111/2, Street 16 Khayaban-	Mr. Farooq Saleem, 141/2, Street 16 Khayaban-e-
e-Muslim DHA 6, Karachi. CNIC:42301-	Muslim Phase-6, DHA Karachi. CNIC:42301-
3842441-9.	3842441-9.
Mr. Khaleeq-ur-Rehman Khan Yousufi, House	Mr. Iftikhar Hussain Shirazi, 2-Khayaban-e-Ghazi
No.150/1, 35 th Street Khayaban-e-Muslim	Phase-V, DHA, Karachi. CNIC: 42301-0948515-
D.H.A VI, Karachi.	3.
, and the second	

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:-

Ex	isting name (s) of Proprietors/Dirctors.	Proposed name (s) of Proprietors/Directors.		
1.	Mr. Mobeen Alam, House No.32/2/2,	1.	Mr. Rashid Abdullah, Houe No.5, Block	
	Commercial lan,e Phawe 4, DHA, Karachi.		7/4, DMCHS, Tipu Sultan Road, Karachi.	
	CNIC:42301-6775803-3.		CNIC:42201-1132967-1.	
2.	Mr. Muhammad Sajid, House No.LS-158, St.	2.	Mr. Adnan Asdar Ali, House No.B-40/1,	
	No. Korangi, Sector 31-E, Lucknow		Block 3, Clifton, Karachi. CNIC:42301-	
	Cooperative Housing Soceity, Karachi		1091664-3.	
	CNIC:42201-880829-1	3.	Mr. Syed Nadeem Ahmad, House No.86/1,	
3.	Mr. Tahir Ahmed, House No.6/6, 16 model		St. 24, Khayaban-e-Sehar, Phase 6, DHA,	
	colony, Karachi. CNIC:42201-0169711-5.		Karachi. CNIC:42301-0869989-9.	
4.	Mr. Zubair Razzak Palwala, House No.27-	4.	Mr. Zubair Razzak Palwala, House No.27-	
	B/11, Street No. Q, Phase 6, DHA, Karachi.		B/11, Street No. Q, Phase 6, DHA, Karachi.	
	CNIC:42201-5080780-3.		CNIC:42201-5080780-3.	
5.	Mr. Moujood ul Hasan, House No.555, St.6	5.	Mr. Ayaz Abdullah, House No.210, St.	
	DOHS, Phase 1, Malir Cantt, Karachi.		No.2, AFOHS, Falcon Complex, Main	
	CNIC:35202-2434522-3.		Shahrah-e-Faisal, Karachi. CNIC:42201-	
6.	Dr. Imtiaz Haider, C-16, Gulshan-e-Iqbal,		8726172-1.	
	Block 4, Karachi East, Karachi: CNIC:42000-	6.	Ms. Shaista Khaliq, House No.54/1, St	
	3720085-3.		No.B-6 th , Phase 5, DHA, Karachi.	
			CNIC:42301-8797867-2.	
		7.	Mr. Asad Abdullah, House No.2, Dehli	
			Mercantile Soceity, Block 7/B, Karachi.	
			CNIC:42201-8964822-9.	
	isting Address		oposed Address	
	Floor, NICL Building, Abbasi Shaheed Rpad,		ction D, 2 nd Floor, One IBL Centre, Plot	
Ka	rachi.		o.1, Block 7 & 8, DMCHS, Tipu Sultan Road,	
		Of	f 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:-

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

Dro	evious name (s) of Proprietors/Dirctors.	Ne	w Approved name (s) of
Trevious name (s) of Prophetors/Difetors.			w Approved name (s) of oprietors/Directors.
1.	Mr. Mobeen Alam, House No.32/2/2, Commercial lan,e Phawe 4, DHA, Karachi.		Mr. Rashid Abdullah, Houe No.5, Block 7/4, DMCHS, Tipu Sultan
	CNIC:42301-6775803-3.		Road, Karachi. CNIC:42201-
2.	Mr. Muhammad Sajid, House No.LS-158,		1132967-1.
	St. No. Korangi, Sector 31-E, Lucknow	2.	Mr. Adnan Asdar Ali, House No.B-
	Cooperative Housing Soceity, Karachi CNIC:42201-880829-1		40/1, Block 3, Clifton, Karachi. CNIC:42301-1091664-3.
3.	Mr. Tahir Ahmed, House No.6/6, 16 model	3.	Mr. Syed Nadeem Ahmad, House
	colony, Karachi. CNIC:42201-0169711-5.		No.86/1, St. 24, Khayaban-e-Sehar,
4.	Mr. Zubair Razzak Palwala, House No.27-		Phase 6, DHA, Karachi.
	B/11, Street No. Q, Phase 6, DHA,		CNIC:42301-0869989-9.
	Karachi. CNIC:42201-5080780-3.	4.	Mr. Zubair Razzak Palwala, House
5.	Mr. Moujood ul Hasan, House No.555,		No.27-B/11, Street No. Q, Phase 6,
	St.6 DOHS, Phase 1, Malir Cantt, Karachi.		DHA, Karachi. CNIC:42201-
	CNIC:35202-2434522-3.		5080780-3.
6.	Dr. Imtiaz Haider, C-16, Gulshan-e-Iqbal,	5.	Mr. Ayaz Abdullah, House No.210,
	Block 4, Karachi East, Karachi:		St. No.2, AFOHS, Falcon
	CNIC:42000-3720085-3.		Complex, Main Shahrah-e-Faisal,
			Karachi. CNIC:42201-8726172-1.
		6.	Ms. Shaista Khaliq, House
			No.54/1, St No.B-6 th , Phase 5,
			DHA, Karachi. CNIC:42301-
			8797867-2.
		7.	Mr. Asad Abdullah, House No.2,
			Dehli Mercantile Soceity, Block
			7/B, Karachi. CNIC:42201-
			8964822-9.

5. <u>SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.</u>

5.1.

The case of M/s Ghazali Brothers, Karachi for the below mentioned product was considered in the 12^{th} MDB meeting held on 13-05-2019 and approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017:-

	Name and	Manufacture Details	Name of Medical	Brief	Remarks
S.	Addresses of		Device with sizes/	Description	
No	Establishment		Class/Shelf Life		
	M/s Ghazali	Manufacturer:	SpineLP Disposable	Anaesthesia	Approved subject
	Brothers, 1st	M/s Zhejiang Kindly	Anaesthesia Needles	(Spinal	to foreign
	Floor, Azzainab	Medical Devices Co.,		Needle)	inspection abroad.
	Court Compbell	Ltd., No.758, 5 th Binhai	Class D		The Board also

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

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 11th 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)	Legal Manufacturer/ Manufacturing Site: 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	Approved.
2.	-do-	Legal Manufacturer/ Manufacturing Site:	YVOIRE Classic Plus	Dermal Filler, Synthetic-Fluid	Approved.

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

5.3.

The case of M/s Life-Tec, Islamabad for the below mentioned product was considered in the 15^{th} 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	Manufacturer:	Nigale Plasma	The Plasma
	Unit B, 1 st Floor,	M/s Sichuan Nigale	Separator(Model: NGL XJC	Separator
	Block 20-D, G-8,	Biotechnology Co, Ltd,	2000)	takes
	Markaz,	No.28, Kuixing Road,		advantages of
	Islamabad.	Dongxi town, 641400,	Class: C	density
		Jianyang, Sichuan, People's		difference of
	ELI-00155	Republic of China	Service life: 5 years	blood
				components of
		FSC China valid till 3 rd July,	Fee submitted: Rs 25,000/-	finish the
		2020		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.

	M/s Life-Tec			
		Manufacturer:	Nigale Disposable Blood	Intended to be
	Unit B, 1st Floor,	M/s Sichuan Nigale	Components Apheresis Set	used with
	Block 20-D, G-8,	Biotechnology Co, Ltd,	(Model: P-2000IA)	blood
	Markaz,	No.28, Kuixing Road,		component
	Islamabad.	Dongxi town, 641400,	Class: C	separating
		Jianyang, Sichuan, People's		machine or
	ELI-00155	Republic of China	Shelf Life: 4 years	blood cell
				separating
		FSC China valid till 8-5-	Fee submitted: Rs 50,000/-	machine for
		2020		collection of
				blood platelet,
				collection of
				plasma,
				collection of
				red cell.
				Sterile, single-
				use
3.	M/s Life-Tec	Manufacturer:	Nigale Blood Component	Medical
	Unit B, 1st Floor,	M/s Sichuan Nigale	Separator (NGL XCF-3000)	equipment
	Block 20-D, G-8,	Biotechnology Co, Ltd,	Separator (NGL ACI -3000)	that takes
	Markaz,	No.28, Kuixing Road,	Class: C	advantage of
	Islamabad.	Dongxi town, 641400,	Class. C	density
	Islamadau.	Jianyang, Sichuan, People's	Service life: 5 years	difference of
	ELI-00155	Republic of China	Service inc. 5 years	blood
	ELI-00133	Republic of Chilla	Eas submitted: Do 50 000/	
		ESC China and id 4:11 2rd Index	Fee submitted: Rs 50,000/-	components to
		FSC China valid till 3 rd July,		perform
		2020		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:-

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description
1	M/s Nisa SF Private Limited, 10-KM Muridke- Shaikhupura Road, Muridke District Sheikhupura, Punjab, Pakistan (ELM-0001)	Sizes: 1ml with 26Gx½"(0.45mm x 13mm) 1ml with 22G (0.7Mm x 30mm) 2ml with 26G (0.7mm x 40mm) 3ml with 24G X 1 " (0.55mm x 25mm) 5ml with 23G X 1 " (0.6mm x 25mm) 10ml with 21G X 1¼"(0.8mm x 32mm) 20Ml with 21G X 1½"(0.8mm x 38mm) Exemption for local manufacture upto 31st March, 2021 for 2ml, 2.5ml, 3ml and 5ml . Class B Shelf Life: 3 years Rs. 25,000/-	Disoposable Hypodermic Syringes
2	-do-	Venous Disposable Infusion Set N.S.002 Class B Shelf Life: 3 years Rs. 25,000/-	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 prevelence 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 percapita 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 investgations carried out for the 2019 HIV outbreak in Larkana suggest a strong assocation between unsafe injections (reuse of syringes and IV drip set) and transmission of injection. Prescription of unnecessary innjection and injections given with reuse injection equiment 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. Minisitry 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 17th 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 32nd 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 31st January, 2021 and 31st July, 2021 respectively.

8. <u>APPLICATIONS FOR GRANT OF ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICE.</u>

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.	Manufacturer: M/s Arrow International, Inc (Subsidiary of Teleflex, Inc), 2400 Bernville Road Reading, PA 19605, USA. Manufacturing Site (s): 1. M/s Arrow International de Chihuahua S.A de C.V, Ave, Washington 3701, Interior Circuito Industrial Alta Technologia Edificios 40 and 2,k Colonia Panamericana Chihuahua, Chihuahua CP31200, Mexico.	CS-12702-E,CS- 12802,CS-15802- E,CS-16702,CS- 16702-E,CS- 17702,CS-17702- E, CV- 12702,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.	-do-	CS-12553-J,CS-12703-E,CS-12703,CS-12853-E,CS-14703,CS-15703-E,CS-15853-E,CS-15853-E,CS-15853-J,CV-12703,CV-12703-E,CV-14703,CV-14703-E,CV-15703-E,CS-15503-M, LS-15853, ML-00703, SS-14703, CS-15403, CS-1553-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.	Name of Medical Devices	Quantity
No.		
1.	Vacuum Sealing Drainage Dressing Kit	04 Pcs
2.	Wound Drainge Reservoir	02 Pcs
3.	Vacuum Sealing Dressing Kit	03 Pcs

Internal prupose 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 faciliates complete would drainage and eliminates dead space, resulting in a decreased would area, and enhanced formation of granulation tissue.

- 2. **Wound Drainage Reservoir.** Would 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 faciliates complete would drainage and eliminates dead space, resulting in a decreased would 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:-

S.No	Reg.No.	Name of medical device(s)		
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 Polyster		
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 Would 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	Surgiadac (uncoated Braided Polyster)			
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 Stempler			
29.	MDIR-0001360	COVIDIEN Bone Wax (Heamostatic Bone Wax) Surgical Heamostatic 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 ar manufctured 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 discused 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 discused 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. <u>AMENDMENT IN NAME OF MANUFACTURER OF M. DIOR (MALE LATEX CONDOM) REGISTERED WITH DRAP ENLISTMENT/REGISTRATION NO. MDIR-0001294 DATED 13-02-2020.</u>

M/s M&M Pharma, 1st Floor, Javed Plaza, Opp Gate No.2, Pepsi Factory, Gurumangat Road, Gulberg II, Lahore has applied for the amendment in the name of legal manfacuturer 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: -

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
MDIR-0000009	Xience Prime Everolimus Eluting Coronary Stent System	Legal Manufacturer: M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA	02 Year	03 Years
		Manufacturing Site: 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		
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	Manufacturer: 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 Sautures with needle (non absorbable)	-do-	03 Year	05 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.

13. <u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES ON PRIORITY BASIS).</u>

S.	Name and	Manufacture	Name of	Brief Description
#	Addresses of	Details	Medical Device	
	Establishment		with	
			sizes/Class/Shel	
			f Life	
1.	M/s. Hospital	Legal Manufacturer:	Yu Shou Auto	Auto-disable
	Services & Sales,	M/s Wuxi Yushou	Disable Syringes	syringes- auto
	13-C Annexe,	Medical Appliances		destroyed after
	Block 6,	Co., Ltd No.115	Class-B	injection.
	P.E.C.H.S,	Nongxinhe Road,		
	Karachi.	Dongbeitang Town,	Shelf Life: 5	
		Xishan District-	years	
	(Renewal)	214191, Wuxi City,	Sizes/ Codes:	
		Jiangsu Province, P.R.	0.05ml	
		China.	0.1ml	
			0.5ml	

FSC China valid till	1ml
27-12-2020	2ml
	3ml
FSC Germany expired	5ml
on 01-10-2013	10ml

Decision: The MDB approved the product subject to provision of shortcomings: MRP of the device

Reference country FSC expired.

QMS certificate expired.

Labels missing

2.	AGP Limited, B-	Legal Manufacturer:	Oneject Auto	Polypropylene syringe
	23-C, SITE,	M/s PT. Onject	Disable Syringe	with latex free rubber
	Karachi	Indonesia Olympic	1ml, 2ml, 3ml &	gasket and stainless
	(ELI-00571)	Raya Kav. B9	5ml	needle
		Kawasan Industri		
		Sentul Bogor 16810-	Class B	
		Indonesia		
			Shelf Life: 05	
		FSC Indonesia valid	Years	
		till		
		(15-06-2022)	Rs.25,000/-	
		WHO prequalified		

Decision: The MDB approved the product subject to provision of mentioned shortcomings:

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	Legal Manufacturer:	Sterile Auto-	Sterile Auto-Disable
	Pharmaceutical,	M/s Jiangxi Sanxin	Disable Syringe	Syringe for fixed dose
	Suit No.16,	Medtec Co., Ltd.,	for fixed dose	immunization
	Beaumont Plaza,	No.999, Fushan Road,	immunization	
	6-CL-10,	Xiaolan Economic	0.5ml, 0.1ml,	
	Beaumont Road,	Development Zone	1ml, 2ml, 3ml &	
	Karachi	Nanchang Jiangxi,	5ml	
	(ELI-	China		
			Class B	
		FSC China Valid Till		
		(07-10-2021)	Shelf Life: 05	
		WHO prequalified	Years	

	Rs.25,000/-	
	13.23,000/-	

Decision: The MDB approved the product subject to provision of mentioned

shortcomings: Original and valid FSC in the country of origin clearly mentioning the product, duly attested.

Labels of all applied sizes, approved in the country of origin.

Notarized QMS & FQA certificates, as the provided documents are without notarization

4.	M/s Zhangjiakou	Legal Manufacturer:	Tie Shan Lan	Needle Retractable	The same
	Dongfang	M/s Guangdong Haiou	Needle	Safety Syringe Single	manufacturer
	Pharmaceutical	Medical Apparatus	Retractable Safety	Use Sterile Needle	's syringes
	Pakistan (Pvt)	Co., Ltd., Nanyuan	Syringe	Retractable Safety	are already
	Ltd., D-2, 2nd	Industrial Zone, North		Syringe with needle	applied by
	Floor, Westland	Liusha, Puning City,	Class B		hospital
	Trade Centre,	Guangdong Province,			services,
	Plot No.C-5,	China	Shelf Life: 05		Lahore but
	Block 7/8		Years		with another
	KCHSU,	FSC China Valid Till			brand name.
	Shaheed-e-Millat	(07-10-2021)	Rs.25,000/-		
	Road, Karachi				
	(ELI-00374)				

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 & Sales, 13-C, Annex, Block PECHS, Karachi with brand name of Haiou Auto Disable Syringe with Needle.

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

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

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

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

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

			Fee submitted: Rs.		
10.	M/s Hoora Pharma (Pvt) Ltd., WH-01- 20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037)	Legal Manufacturer/ Manufacturing Site: M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, UK (FSC Ireland Valid Till11-09- 2024)	IMMULITE 2000 Rubella IgG Assay Kit Class C IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB2 Shelf Life: 12 Months IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB6 Shelf Life: 12 months	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
			Fee submitted: Rs. 50,000/-		
11.	M/s Tech Zone, 764 Askari 9, Zarar Shaheed Road, Cantt, Lahore, Ware House: Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040	Legal Manufacturer & Manufacturing Site: Pikdare S.p. A Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO Italy. FSC Italy Issued on 24.05.2019	PIC Solution INSUMED [Insulin syringes with needle rigidly fixed (auto protect)] Class B Sizes: 0.3ml, 0.5ml, 1.0 ml Codes: As per FSC Italy dated 24-05- 2020 Shelf Life 5 years. Fee submitted: Rs. 25,000/-	Sterile, single- use syringe for insulin administration	Approved
12.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas II,	Manufacturer: 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-	Manufacturer: 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	Approved
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.	Approved 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	Approved

		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	Approved
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.	Approved
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 TM 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	Approved

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

21.	-do-	China valid till 01-02-2020 Manufacturer: M/s. Huaian Angel Medical Instruments Co., Ltd., 19 East Zhuhai Road, Huaian, Jiangsu 223001, China. Export Only Certificate fromChina valid till 01-02-2020	Stay Guard Sutures - Nylon Polyamide (Nylon) suture (Codes not given) Class C Shelf Life: 60 months	plastic surgery; subcuticular; Obstetrics; gynaecology; hepatic. NYLON suture made of nylon refined, the surface smooth and no side effects, etc mainly used in ophthalmolog y and general surgery.	Rejectedas thesutures of this manufacturer are already registered in the name of M/s Zenith International, Karachi
22.	-do-	Manufacturer: 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	Stay Guard Sutures- Polypropylene / Prolene (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.	Rejectedas thesutures 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 LLtd, 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 po sitive airway pressure (CP AP) 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.	Approvedsubje ct to submission of CE marked document.

24.	M/s. Surgi World 303, Muhammad Plaza, College Road, Rawalpindi. (ELI-00212)	Legal Manufacturer: Bard Access System, Inc. 605 North 5600 West Salt Lake City, Utah (UT) USA. Manufacturing Site: 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.	Approved.
25.	-do-	Legal Manufacturer: Bard Peripheral Vascular, Inc. 1625 W 3 rd st Tempe, AZ USA 85281 (FSC US FDA valid till 28-11- 2020)	IMPRA ePTFE vascular Grafts Vascular Grafts Class C Shelf Life: 5 Years Codes As Per FSC	IMPRA ePTFE vascular Grafts are constructed of expanded polytertrafluoro ethylene. They are indicated for use as vascular prostheses.	Approved.
26.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030)	Legal Manufacturer: Ascensia Diabetes Care Holdings AG, Peter Merian- Strasse 90, 4052 Basel, CH Manufacturing site: HTL-STREFA S.A. ul. Lotnicza 21h, 99-100 Leczyca, Poland.	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.	Approved.

		(FSC Switzerland valid 17-10-2022)			
27.	-do-	Legal Manufacturer: Ascensia Diabetes Care Holdings AG, Peter Merian- Strasse 90, 4052 Basel, CH. Manufacturing site: HTL-STREFA S.A. ul. Adamowek 7, 95-035 Ozorkow, Poland. (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.	Approved.
28.	M/s KASBN International, 422-A-1 GULBERG III NEAR GHALIB MARKET LAHORE (ELI-00434)	Legal Manufactuer: NOUVAG AG LOCATED at St. Gallerstrasse 23-25, 9403, Goldach, Switzerland. FSC: Switzerland Valid till 30.07.2022	(NOUVAG) SUCTION PUMP Class B Shelf Life: N/A Codes/ models: 4227-115-4227-230-	The Nouvag suction pumps is used for suction of fluids and secretions.	Approved.
29.	M/s. Ahmad Medix Pvt (Ltd) 129/6 Quaid- e- Aza, Industrial Estte, Township, Lahore. ELI-00380	Legal manufacturer 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 coll the skin, keep the wound moist and prevent from being dry and	Deferred forprovision of reference country Free Sale Certficate or inspection of manufacturer abroad.

				cracked.	
30.	M/s S.Ejazuddin& Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078)	Manufacturer: 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.	Approved. The firm shall submit FQA certificate before issuance of registration letter.
31.	-do-	Manufacturer: 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 mentioed 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 recommend for monitoring the average blood glucose levels, for long-term care of people with diabetes.	Deferred for provision of reference country Free Sale Certficate or inspection of manufacturer abroad.
32.	M/s Mana & Co., Office No. 401, 4 th floor, Masood chamber Shahrah e Liaqat, Karachi., Karachi (ELI-00280) [2820]	Legal Manufacturer: 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	Deferred for provision of reference country Free Sale Certficate or inspection of manufacturer abroad.

33.	-do-	Haicang District, Xiamen City, Fujian Province China FSC China Valid Till (07-042022) Legal Manufacturer: 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 (07-042022)	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	Deferred 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	Legal Manufacturer Becton, Medical (S) Pte Ltd 30 Tuas Avenue 2, Singapore 539461 Singapore FSC: Singapore issuance 20-11-2018	BD TM 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.	Deferred for provision of reference country Free Sale Certficate or inspection of manufacturer abroad.
35.	M/s. AL-Walli Care Concepts	Legal Manufacture:	CONIC ONE (PTCA BALLOON	CONIC ONE PTCA is	Approved.

06 A 11 a a		CATHETED	indicated in	1
86-Allama	CONIC	CATHETER)	indicated in	
Iqbal Road	CONIC	C1-150/125X15	patients with	
Garhi Shahu	VASCULAR	C1-150/125X20	significant	
Lahore	TECHNOLOGY,		coronary artery	
EL 1 00206	S.A. Via Carlo	C1 150/125V15	disease who are	
ELI-00386	Maderno, 23	C1-150/125X15	acceptable	
	CH-6901 Lugano, Switzerland	C1-150/125X20	candidates for	
	Switzeriand	C1-225/175X30	coronary artery	
	M 6 4	C1-200/175X15	bypass graft	
	Manufacturing	C1-250/200X30	surgery and	
	Site:	C1-225/200X15	who meet one of the	
	CONIC	C1-275/225X30		
	CONIC	C1-250/225X15	following selection	
	VASCULAR	C1-300/250X30	criteria.	
	ESPANA, S.L.	C1-275/250X15		
	C/ENTRERRIOS,	C1-325/275X30	Atherosclerotic	
	N 9 bajo 15220	C1-300/275X15	coronary artery disease that is	
	Ames, Span.	C1-350/300X30	accessible with	
	FSC: Switzerland	C1-325/300X15 C1-400/350X30		
	rac. awitzeriand	C1-400/350X30 C1-350/325X15	a dilation catheter.	
	Valid till:	C1-450/400X30	ii.	
	11.06.2022	C1-400/375X15	Corona	
	11.00.2022	C1-225/175X35		
		C1-223/175X33 C1-200/175X20	ry artery disease of the	
		C1-250/200X35	native coronary	
		C1-225/200X33	arteries and/or	
		C1-225/200X20 C1-275/225X35		
		C1-273/225X33 C1-250/225X20	coronary artery bypass grafts of	
		C1-230/223X20 C1-300/250X35	some patients	
		C1-275/250X20	who have	
		C1-275/230X20 C1-325/275X35	previously	
		C1-323/275X33 C1-300/275X20	undergone	
		C1-350/273X20 C1-350/300X35	coronary artery	
		C1-325/300X33	bypass graft	
		C1-400/350X35	surgery and	
		C1-400/330X33 C1-350/325X20	who have	
		C1-450/400X35	recurrence of	
		C1-400/375X20	symptoms and	
		C1-225/175X40	(a) progression	
		C1-225/175X25	of disease or	
		C1-250/200X40	(b) stenosis and	
		C1-250/200X25	closure of the	
		C1-275/225X40	grafts	
		C1-275/225X25	8	
		C1-300/250X40		
		C1-300/250X25		
		C1-325/275X40		
		C1-325/275X25		
		C1-350/300X40		
		C1-350/300X25		
		C1-400/350X40		
		C1-400/350X25		
	•	•		

	1	T	I		<u> </u>
			C1-450/400X40		
			C1-450/400X25		
			C1-200/150x25		
			C1-200/150X25		
			Class D		
			Shelf Life:2.5 Years		
36.	-do-	Legal Manufacture:	CLEVER	Clever PTCA	Approved.
		CONIC	PTCA BALLOON	is indicated in	TT
		VASCULAR	CATHETER	patients with	
		TECHNOLOGY,		significant	
		S.A. Via Carlo	Size Variants:	coronary artery	
		Maderno, 23, CH-	CV-200-10	disease who are	
		6901 Lugano,	CV-200-15	acceptable	
		Switzerland	CV-200-15 CV-200-25	candidates for	
		Switzeriand	CV-200-23 CV-225-10	coronary artery	
		Manufacturing	CV-225-10 CV-225-15	bypass graft	
		Site:	CV-225-13 CV-225-20	• •	
		Site.	CV-225-20 CV-225-25	surgery and who meet one	
		CONIC			
		CONIC	CV-225-30		
		VASCULAR	CV-200-35	following	
		ESPANA, S.L.	CV-225-40	selection	
		C/ENTRERRIOS,	CV-250-15	criteria.	
		N 9 bajo 15220	CV-250-20	Atherosclerotic	
		Ames, Span.	CV-250-25	coronary artery	
			CV-250-30	disease that is	
		FSC: SwitzerLand	CV-250-35	accessible with	
		Validity:	CV-250-40	a dilation	
		11.06.2022	CV-275-10	catheter.	
			CV-275-15	ii.	
			CV-275-20	Corona	
			CV-275-25	ry artery	
			CV-275-30	disease of the	
			CV-275-35	native coronary	
			CV-275-40	arteries and/or	
			CV-300-10	coronary artery	
			CV-300-15	bypass grafts of	
			CV-300-20	some patients	
			CV-300-25	who have	
			CV-300-30	previously	
			CV-300-35	undergone	
			CV-300-40	coronary artery	
			CV-325-10	bypass graft	
			CV-325-15	surgery and	
			CV-325-20	who have	
			CV-325-25	recurrence of	
			CV-325-30	symptoms and	
			CV-325-35	(a) progression	
			CV-325-40	of disease or	
			CV-350-10	(b) stenosis and	
			CV-350-10 CV-350-15	closure of the	
	1	l .	C V -330-13	Closule of the	

		Γ	CV 250 20	Ct -	
			CV-350-20 CV-350-25	grafts	
			CV-350-25 CV-350-30		
			CV-350-35		
			CV-350-35 CV-350-40		
			CV-400-10		
			CV-400-15		
			CV-400-20		
			CV-400-25		
			CV-400-30		
		ļ	CV-400-35		
		ļ	CV-400-40		
			CV-450-20		
		ļ	CV-450-25		
			CV-450-30		
			CV-450-35		
			CV-450-40		
			Class D		
			C1 1CT :C 0.7		
			Shelf Life: 2.5 years		
37.	M/s	Legal	Wellex (IV Cannula	IV cannula	Approved.
	Sultansons, 133	Manufacturer:	with Port)	with port is	
	Kutchi Gali	M/s Wellex		used for	
	No.1, Marriott	Company, Cairo-	Class B	infusion of I.V	
	Road, Karachi	Ismailia Desert		solution	
	(ELI-00051)	Road, Ismailia	Shelf Life: 05 Years	suitable for	
	[2726]	Public Free Zone,		administration	
		41639 Ismailia	Rs.25,000/-	via peripheral	
		City, Egypt		vein.	
		Limited Company.	Codes/ sizes as per		
			FSC		
		FSC Egypt			
		Issuance Date			
		18-02-2020			
		Reference country			
		FSC Germany			
		issuance 11-11-			
		2019			
38.	M/s. LENS	Legal	Soft contact lense	Lens	Deferred for
	House	Manufacturer:	daily wear		provision of
	3 rd Floor,	Polytouch Co.Ltd			reference
	Musarat Plaza,	129-4 Hyeopseok 2	Class C		country Free
	Alnak Market	gil			Sale Certficate
	Shah ALam,	Namcheonmyeon,	Shelf Life 5 years.		
	Market Lahore.	Gyeongsan si,	,		or inspection
		Gyeongsangbuk-do	Models:		of
	ELI-00397	Republic of Korea.	NK		manufacturer
	, , , ,	T 22 22 22020.	New comfort		abroad.
		FSC Korea	Comfort 60		
	I			1	1
1		Issuance 03-02-			l l

		2020			
39.	M/s. Chemical House 6-C Sikandar Malhi Road, Canal park, Gulberg II, Lahore. ELI-00156	Legal Manufacturer 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 # 72561, 72562) (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.	Approved. The firm shall submit the updated LOA before issuance of registration letter.
40.	M/s. Novatek Pakistan. P-20 Ist Floor, Chenab Market, Susan Road, Madina Town, Faisalabad. (ELI-00454)	Legal Manufactuer: 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	Airocide 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.	Deferred 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
41.	M/s Balta Impex, SH.40, Namco Centre, Cambell Street, Karachi. (ELI-00170)	Legal Manufacturer: 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.	Deferredforpr ovision of reference country Free Sale Certficate or inspection of manufacturer abroad and submission of valid FSC.

42.	-do-	Legal	Golden +	A tracheal	Deferred for
		Manufacturer:	Endotracheal tubes	tube is	provision of
		Haiyan Kangyuan		a catheter that is	reference
		Medical Instrument	Class B	inserted into	country Free
		Co., Ltd		the tracheal for	Sale Certficate
		Songpodong Rd.,	Shelf Life: 5 Years	the primary	or inspection
		Shengdang Town,	Sizes:	purpose of	of inspection of
		Haiyan Zhejiang	ID2.0, ID2.5, ID3.0,	establishing and maintaining a	manufacturer
		Province, China.	ID3.5, ID4.0, ID4.5,	patent airway	abroad and
		(Fac city Maria	ID5.0, ID5.5, ID6.0,	and to ensure	submission of
		(FSC China Valid	ID6.5, ID7.0, ID7.5,	the	valid FSC.
		till 08-07-2019)	ID8.0, ID8.5, ID9.0, ID9.5, ID10.0	adequate exchan	valid FSC.
			Rs.25,000/-	ge of oxygen an	
			Ks.25,000/-	d carbon	
12	M/s. Renacon	M64	D AX/ E\$-4-1-	dioxide.	D.C 1 C
43.	Pharma Ltd.	Manufacturer	Renav AV Fistula Needle	Fistula Needle for	Deferred for
	House No,3	M/s. Jiangxi Sanxin Medtec Co., Ltd, N	(Fistula Needle for	Hemodialysis.	provision of
	Street No 1, 18	o.999 Fushan Road,	Hemodialysis)	Tiemodiarysis.	reference
	Km, Ferozepur	Xiaolan Economic	Tiemodiarysis)		country Free
	Road, Mujahid	Development Zone,	Class C		Sale Certficate
	Colony Lahore.	Nanchang, Jiangxi,			or inspection
	,	330200, P.R.	Shelf Life: 02 years		of
	ELI-00177	China.			manufacturer
			Models & sizes:		abroad and
		FSC China	A type, B type		submission of
		Valid till 18-10-	1.8mm (15G), 1.6mm (16G), 1.4mm (17G),		valid FSC.
		2020	1.2mm (18G)		
			1.211111 (100)		
44.	M/s Global	Legal	ichroma TM Ferritin	Ichroma TM	Approved
	Health Care,	Manufactuer:		Ferritin	
	Midway		Test for Ferritin	fluorescence	
	Commercial	Boditech Med Inc.		Immunoassay	
	Plaza No. 20,	43, Geodudanj i 1-	Class B	(FIA) for	
	BackSide of	gil, Dongnae-	G1-161 16 0034 4	quantitative	
	prism Arcade	myeon,	Shelf Life: 20 Months	determination	
	2, Phase 7 Bahria Town,	Chuncheon-si, Gangwon-do,	Control stability studies of kit and	of Ferritin in human	
	Rawalpindi.	Korea.	control	Serum/plasma.	
	Kawaipiliui.	ixoroa.	Control	It is useful as	
	(ELI-00086)	(FSC Korea	Codes:	an aid in	
		Issuance 19-10-	CFPC-32	quantifies	
		2018)		human ferritin.	
		FSC Belgium		For in vitro	
		issuance 20-11-		diagnostic use	
		2019		only.	
45.	-do-	Legal	King Malaysia	Latex surgical	Deferred for
		Manufacturer:	(0, 1 5 1 1	gloves is made	provision of
		Monton Malass	(Sterile Powdered	from 100%	reference
		Maxter Malaysia Super Max Gloves	Latex Surgical Gloves)	natural rubber and sterile by	country Free
		Manufacturing	Gloves)	gamma	Sale Certficate

48.	Jami, Street No.9, DHA Phase 07, Karachi M/s Zenith International Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. ELI: 00090. 127-(K)-MD	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 Manufacturer: M/s Zheijiang Bangli Medical Products Co., Ltd., No. 118 Yuegui South Road City, West New District 321300 Yongkang City, Zhejiang Province, China	Class C Shelf Life: 5 Years Sizes & Codes: P53S Rs.50,000 PERFECT PLAST, Disposable Plaster. Shelf Life: 60 months. Class-A.	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. Disposable Plaster	Approved subject to provision of valid ISO 13485/ GMP certificate &FSC of country of origin.
49.	-do-	Manufacturer: 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	PERFECT Disposable Heparin Cap. Shelf Life: 60 months. Class-B.	Disposable Heparin Cap	Approved 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	Legal Manufacturer: M/s. PLASTI- MED	UMBILICAL CORD CLAMP. Class: B	The umbilical cord clamp allows the passage of	Approved subject to inspection of manufacturer

51.	Dawn Plaza, Bank Road, saddar, Rawalpindi M/s deKhon, 11-C Old FCC, Ferozpure Road, Gulberg- III, Lahore. ELI-000317.	Deri OSB Mahallesi Yn Sanayi Cad. No: 13 Tuzla/Istanbul Turkey. FSC Turkey Date of issue.3rd April,2017. Legal Manufacturer TRB Chemedica Ag Otto- Lilienthal-Ring 26, D-85622 Feldirchen/Munch en, Germany Production Facility (VISmed Gel) Pharma Stulln GmbH WerksstraBe 3 92551 Stulln, Germany Pharmaster Z I ErsteinKrafft 67150 Erstein France.	i. Vismed ® Gel Multi. (Sodium Hyaluronate	oxygenated blood from the placenta to the fetus through the abdomen. Sodium Hyaluronate 0.3% GEL	abroad and submission of original fee slip endorsed by Directorate Budget & Account, DRAP. Approved the product; Vismed ® Gel Multi. (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-	France. FSC: Germany Date of Issue: 14.06.1993 Legal	OZODROP ®	OZODROP is	Approved;
52.	-40-	FB Vision s.r.I Via Piceno Aprutina 47, 63100 Ascoli Piceno Production Facility Name of Firm OMISan Farmaceutici S.R.I Address: VIA Galileo Galilei, 00012 Guidonia	Ophthalmic solution. {Hypromellose & 10% Liposomes}. Class: C. Shelf Life: 24-Monhs.	a protective, lubricating, moisturising and soothing ophtalmic solution for the ocular surface, based on hypromellose, liposomes and ozonated vegetable oil useful for: Facilitating reparative	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.	M/s. Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi.	Legal Manufacturer: 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)	Disposable with Needle (30ml & 50ml) Class-B	Disposable Syringes with Needle	Deferred; 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.	-do-	Legal Manufacturer: 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	Disposable Syringes with Needle (1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml) Class-B.	Disposable Syringes with Needle	Deferred; 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

55.	-do-	Till (23-07-2019) Legal Manufacturer: M/s Bao Health Medical Instrument Co., Ltd., 2nd Floor of 8-2 Building,	Bao Helath (Ostomy Care Bag) Class B	It is used to collect output from a stoma	country of origin. In case of failure to comply, the case will be considered for rejection by MDB. Deferred; firm asked to provide the original fee slip/ or importer's copy; Provide, justifiable
		Gaoqiao Industrial Zone, Tongxiang, Zhejiang, P.R. China FSC China Valid Till (19-07-2020)			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.
56.	M/s.Abbott Labs. (Pakistan) Ltd.Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.	Legal Manufacturer: M/s Abbott Laboratories, 1921 Hurd Dr Irving, TX 75038, USA FSC USFDA Valid Till (03-03-2021)	TRANSFERRIN (IVD Cluster for Anemia Diagnosis.) Shelf- life: 13months. Class B	IVD Cluster for Anemia Diagnosis	Approved; 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.	ALINITY c ICT Serum Calibrator. Shelf- life: 15months. Class B	ICT Serum Calibrator	Approved the product; ALINITY c ICT Serum Calibrator. subject to provision of ISO-13485,

1		FSC USFDA			MRP, original
		Valid Till			agency
		(08-02-2020)			agreement and FSC.
58.	-do-	Legal	ARCHITECT Anti-	The Architect	Deferred ; for
30.	uo	Manufacturer:	CCP	Anti-CCP	submission of
		Abbot GmbH &	IVD-Reagent Kit.	assay is a	ISO-13485/
		Co, Kg Max-		chemiluminesc	GMP certificate,
		Planck-Ring 2 65205 Wiesbaden	Shelf Life: 18 Months.	ent	MRP, technical
		Germany.	Class B	microparticle immunoassay	information of
		Germany.	Class B	(CMIA) for	QC. And current
		(FSC Germany		semi-	status of the
		Issuance 14-10-		quantitative	product in
		2016)		determination	Germany or
				of the IgG class of	FSC of any SRA country.
				autoantibodies	country.
				specific to	
				cyclic	
				citullinated	
				peptide CCP in human serum	
				or plasma on	
				the architect	
				system	
59.	1	.		iSystem.	
		000	A I INITY Anti (YD	The elimiter	Annuovade
39.	-do-	Legal Manufacturer:	ALINITY Anti-CCP IVD-Reagent Kit.	The alinity Anti-CCP	Approved; subject to
39.	-do-	Manufacturer: Abbot GmbH &	ALINITY Anti-CCP IVD-Reagent Kit.	The alinity Anti-CCP assay is a	Approved; subject to provision of
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max-		Anti-CCP	subject to provision of ISO-13485,
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent	subject to provision of ISO-13485, MRP, original
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden	IVD-Reagent Kit.	Anti-CCP assay is a chemiluminesc ent microparticle	subject to provision of ISO-13485, MRP, original agency
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent	subject to provision of ISO-13485, MRP, original
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi-	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination of the IgG class of autoantibodies	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination of the IgG class of autoantibodies specific to	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination of the IgG class of autoantibodies specific to cyclic	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination of the IgG class of autoantibodies specific to cyclic citullinated	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent microparticle immunoassay (CMIA) for semi- quantitative determination of the IgG class of autoantibodies specific to cyclic	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent 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	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent 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	subject to provision of ISO-13485, MRP, original agency agreement and
39.	-d0-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent 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	subject to provision of ISO-13485, MRP, original agency agreement and
60.		Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10- 2016)	IVD-Reagent Kit. Shelf Life: 13-Months.	Anti-CCP assay is a chemiluminesc ent 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	subject to provision of ISO-13485, MRP, original agency agreement and FSC.
	-do-	Manufacturer: Abbot GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-	IVD-Reagent Kit. Shelf Life: 13-Months. Class B	Anti-CCP assay is a chemiluminesc ent 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.	subject to provision of ISO-13485, MRP, original agency agreement and FSC.

61.	-do-	Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 19-07-2018) Legal Manufacturer: Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany.	Shelf Life: 15 Months. Class B ALINITY i C- Peptide & Insulin IVD-Reagent Kit. Shelf- life: 11-months Class B	Reagent Kit ALINITY i C- Peptide & Insulin IVD- Reagent Kit	provision of ISO-13485 and MRP. Approved the product; ALINITY I C-Peptide.
		(FSC Germany Issuance 12-06- 2019)			
62.	-do-	Legal Manufacturer: Abbott GmbH & Co, Kg Max- Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 26-03-2019)	ARCHITECT c Bilirubin (Total, Direct & In-Direct). IVD Reagent Kit. Shelf Life: 18 Months. Class B	ARCHITECT c Bilirubin (Total, Direct & In-Direct). IVD Reagent Kit	Approved; 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)	ARC c4000 Processing Module, Integrated. (IVD-Machine) Class A	Processing Module, Integrated	Approved 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	CP3000 Main Unit with; CTS CP3000 System A & PC 230V Cuvettes (5000). (IVD-Machine) Class A	CP3000 Main Unit with; CTS CP3000 System A & PC 230V Cuvettes (5000). (IVD-Machine)	Deferred; For provision of following shortcomings/ clarifications: Provide service life protocols & studies, ISO-13485/ GMP certificate,

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

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)	CELL-DYN RUBY Analyzer. (IVD-Machine) Class A	Analyzer. (IVD- Machine)	Approved subject to 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)	ARCHITECT 2000SR Analyzer. (IVD-Machine) Class B	Analyzer. (IVD-Machine)	Approved subject to 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.	M/s Mubarak Vision, 32-A Usman Centre, Shah ALam Market, Lahore. ELI-00045.	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	I-STREAM IOL (ISP60GL). Class: C.	Aspheric Hydrophobic Non-Preloaded Foldable IOL/ Aspheric Hydrophobic Preloaded Foldable IOL	Deferred 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	IRIDEX Ophthalmic lasers + Accessories. Class: C.	Ophthalmic Lasers+Access ories	Deferred 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-	Legal Manufacturer Ret, INc 726- 5, Dureungyuri-ro Ochang-eup, Cheongwon-Gu, Cheongju- si, Chungcheongbuk -do, south Korea FSC: Korea Date of issue 26.09.2019	COMPORT (IOL injector). Class:B.	Ophthalmic Medical Device	Deferred for submission oftechnical info. of QC, clarification regarding The product applied for registration on the basis of free sale certificate of Korea, 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.
72.	M/s PharmEvo (Pvt) Ltd. A- 29, North Western Industrial Zone, Port Qasim Karachi-75020, Pakistan	Legal Manufacturer: Omron Healthcare Co., Ltd. 53, Kunotsubo, Teradocho, Muko Kyoto, 617-0002 Japan. Manufacturing Facility: KunShan Radiant Innovation Co., Ltd. No.20, TaiHong Road, Wusong jiang Development Zone Yushan Town, KunShan city Jiangsu 215300, china. FSC Netherland validity	Omron Gentle Temp 720 Class-B Shelf Life: N/A Code: MC-720-E	Gentle Temp 720 Infrared forehead Thermometer	Approved.

		21-02-2024			
73.	M/s. Cardiac Care 848-C Shadman-I Lahore. ELI-00070	Legal manufacturer Cyro Life, INC.Loacated at 1655 Robert Blvd, NW, Kennesaw, GA, 30144 USA FSC USA Valid Till 14 th March,2021	Bio Glue Surgical Adhesive (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,	Approved.

74.	M/s Lab Link Enterprises, M- 203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi (ELI-00007)	Legal Manufacture: M/s Amsino International, Inc. 708 Corporate Center Drive, Pomona CA 91768, USA Manufacturing Site: M/s Amsino Medical (Kunshan) Co. Ltd, 582 Lidu Road, Qiandeng Town, 215343 Kunshan City, China FSC China Valid Till25-05-2021 FSC Netherland Valid Till	Amsino Burette Set (IV Administration Set) Class B Shelf Life: 05 Years Codes & sizes as per FSC	splenic, hepatic and biliary). Additionally, Bio Glue is used in the fixation of surgical meshes in hernia repair. Burette Set	Approved.
75.	M/s UDL Distribution (Pvt) Ltd., 1-D- 13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073)	Legal Manufacture: M/s Teleflex Medical 3015 Carrington Mill Blvd Morrisville, NC 27560, USA Manufacturing Site: M/s Hudson Respiratory Care Tecate S. de R.L. C.V. (a Teleflex medical company) prolongacion	Weck hem-o-lok automatic clip (ML) Appliers AE05ML, 543965 Class D Shelf Life: 03 Years Rs. 50,000/-	automatic clip (ML) Appliers	Approved.

mission eusebio kino no. 1316, rancho El Descanso tecate, Baja California C.P. 21478, Mexico		
FSC USFDA Valid Till19-06-2021		

15. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

S.#	Name of Firm (s)	Name of	Name of Medical	Brief	Decision
		Manufacturer	Devices.	Description	
1.	M/s Tech Zone, 764	Manufacturer:	Sterile Disposable	Sterile, single-	Approved
	Askari 9, Zarar	GrupA Medikal Tekstil	Surgical Gown	use gowns	
	Shaheed Road,	Tibbi Malzeme.		used in surgery	
	Cantt, Lahore,	Iklimlendrime.San.Ve.	Class A		
		Tic. LTD. STI.,			
	Ware House:	Adalet Mah. Manas	Sizes: S, M, L,		
	Ground Floor, Weal	Bulvari Cd No:	XL, XXL, XXXL		
	House,	47/2601 Bayrakli/Izmir			
	8 Faiz Road,	Turkey	Shelf Life: 3		
	Lahore.		years.		
	ELI-00040	Manufacturing site:			
		GrupA Medikal Tekstil	Fee submitted:		
		Tibbi Malz.	Rs. 5,000/-		
		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			
2.	M/s Atlantic		SAFEPLUS	Non-sterile,	Approved
	Pharmaceuticals,	Manufacturer:	Powder Free Latex	single use,	
	445,	Alliance Rubber	Examination	powder free,	
	Sodawaterwala	Products SDN BHD	Gloves	natural rubber	
	Building, Dr.	LOT 2716 & 2720 MK	Size: Small,	latex	
	Ziauddin Ahmed	7, 14300 Nibong Tebal	Medium, Large,	examination	
	Road, Near Light	Pulau Pinang Malaysia	Extra large, Extra	J.1311111411011	

	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-	Manufacturer: 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	Approved
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.	Approved
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.	Approved

			5,000/-		
6.	-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 CTLS1 Corset Thoraco-Lomber Class: A Ref: 40.330.03 40.330.02 40.330.01 40.330.04 40.330.05 Shelf life: 5 years Fee submitted: Rs. 5,000/-	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	Approved
7.	-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 CLS1 Corset Lumbo- sacral without Belt Class:A Ref: 40.250 40.250.03 40.250.02 40.250.01 40.250.04 40.250.05 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	Approved
8.	-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	MORSA- CYBERG LumboCy CPTI Corset Posturex Class:A Ref: 40.161 40.161.01 40.161.02 40.161.03 40.161.04	Orthopedic Support. Provides a simulative and corrective effect in postural deficiencies and mild kyphosis	Approved

		valid till 19-03-2023			
			Shelf life: 5 years		
			Fee submitted: Rs. 5,000/-		
9.	-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 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 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 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 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 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-	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 WoolCy YD Wool Knee Support Class: A Ref: 20.001.01 20.001.02 20.001.03 20.001.04 20.001.05 Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support. Provide heat and temperature to the knee joint	Approved
13.	-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 SoftCy Scap Clavicula Bandage Class: A Ref: 30.311 30.311.01 30.311.02 30.311.03 30.311.04 Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support to stabilize clavicula fractures	Approved
14.	-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 Thumb Splint Class: A Ref: 60.015 Size: S, M, L, XL, XXL Shelf life: 5 years Fee submitted: Rs.	Orthopedic Support. Inhibits the thumb joint and provides external support, used in De Quarvain syndrome and thumb ligament problems	Approved

			5,000/-		
15.	-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 Silicone Insoles (Full) Class: A Ref: 105.250 105.250.01 105.250.02 105.250.03 105.250.04 Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support. Reduce pain in pes cavus problem. Gives anatomic support and spread all pressure with balance on sole	Approved
16.	-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 SoftCy Arm Sling (Lux) Class: A Ref: 30.301 30.301.01 30.301.02 30.301.03 30.301.04 30.301.05 Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support. Stabilizes he arm in the desired position to immobilize the arm shoulder	Approved
17.	-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 Silicone Toe Separator Class: A Ref: 105.254.01 105.254.02 105.254.03 Shelf life: 5 years	Orthopedic Support. Keeps the thumb stable especially in shoes.	Approved

			Fee submitted: Rs. 5,000/-		
18.	-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 Genu3 Knee Support with Flexible Stays (long) Class: A Ref: 20.103.01 20.103.02 20.103.03 20.103.04 20.103.05 Shelf life:5 years Fee submitted: Rs. 5,000/-	Orthopedic Support. Provides collateral stabilization, protection in sports activities, indicated for strain-sprain, arthritis- bursitis and tendinitis	Approved
19.	-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 CAS1 Corset Abdominal Class: A Ref: 40.420 40.420.01 40.420.02 40.420.03 40.420.04 40.420.05 Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support for abdominal area following abdominal surgeries and prevents sagging in the abdominal area following pregnancy.	Approved
20.	-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.	MORSA- CYBERG NeckCy C3 Cervical Orthosis (Sponge) Class: A Ref: 12.103.01 12.103.02	Orthopedic Support. Inhibits the movements to relieve moderate pain of the neck. Applicable in cases of cervical disc hernia, cervical	Approved

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	12.103.03 12.103.04 12.103.05 Shelf life: 5 years Fee submitted: Rs. 5,000/- 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/-	osteoarthritis and cervical muscle pains. Orthopedic Support. Provides warmth and support to the abdominal area	Approved
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	Approved
23.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK.	MORSA- CYBERG ThermoCy H	Orthopedic Support. Provide wrist	Approved

		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	Approved
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.	Approved
26.	-do-	Manufacturer: MORSA MEDIKAL ORTOPEDI VE MAK.	MORSA- CYBERG ThermoCy H3	Orthopedic Support. Provide wrist	Approved

		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	Wrist Bandage STD Ref: 60.603 Class-A Shelf life: 5 years Fee submitted: Rs. 5,000/-	protective support for sports activities.	
27.	-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 Silicone arch support with fabric Ref: 105.253.01 105.253.02 105.253.03 Class-A Shelf life: 5 years Fee submitted: Rs. 5,000/-	Orthopedic Support. Give support on longitudinal arch in case of impairment base	Approved
28.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209	Legal Manufacturer: M/s. D-tek s.a. Belgium Parc Initialis Rue rene Descartes, 19 BE-7000 Mons BELGIUM. FSC Belgium Issued on 06.02.2019	DrDOT Scanner Dr DOt Software LIC4 Class A Shelf Life: N/A Codes: Software (BE- CA02-097-15) Bluescan 1 (BE- CA02-366-16)	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	Approved

29.	M/s Horizon Group of Company 603- KamranBlock Allama Iqbal Town, Lahore ELI-00140	Legal Manufacturer: 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	been specifically developed for the readingof the strips of the above- mentioned ranges. To be used for cleansing and disinfecting non-invasive medical device.	Approved 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 (ELI-00238)	Legal Manufacturer: M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021).	OXYMAX-SURGI-TAPE Surgical paper Tape. Codes & Sizes as per FSC. Class-A. claimed shelf life: 05-years.	Surgical paper Tape	Approved subject to provision of justificatio n of stability study and approved labelbefore issuance of registration letter.
31.	-do-	Legal Manufacture: M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021).	OXYMAX- Waycare Eye Pad. Codes & Sizes as per FSC. Class-A. claimed shelf life: 05-years.	Waycare Eye Pad	Approved subject to provision of justificatio n of stability study and approved label before

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

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

		Guangzhou, China FSC China Valid Till (08-01-2021)	Class-A. claimed shelf life: 05-years.		n of stability study and approved label before issuance of registration letter.
39.	-do-	Legal Manufacturer M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	OXYMAX Paraffin Gauze Dressing with Chlorhexidine.10 Codes & Sizes as per FSC. Class-A. claimed shelf life: 05-years.	Paraffin Gauze Dressing with Chlorhexidine. 10	Approved subject to provision of justificatio n of stability study and approved label before issuance of registration letter.
40.	-do-	Legal Manufacturer M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China FSC China Valid Till (08-01-2021)	OXYMAX Wound Closure strip. 12. Codes & Sizes as per FSC. Class-A. claimed shelf life: 05-years.	Wound Closure strip	Approved 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	VARISOCKS (Medical elastic antiembolism stocking). Class-A.	Medical elastic antiembolism stocking helps in varicose veins by improvement in circulation	Approved.

Jalan Meru, 40150
Klang Selangor.
FSC: USFDA. Valid
till: 15 th October, 2021

16. <u>CASES APPROVED IN DIFFERENT MEETINGS OF MDB SUBJECT TO PROVISION OF DOCUMENTS.</u>

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

	Igano data	02250040		1
	Issue date	02250040		
	22.01.2019	02250050		
		02250060		
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			03430030		
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			03430080		
			03670050		
			Class D		
			Shelf Life 3 years		
	-do-	Legal	Angiomed	A catherization	MDB
3.		Manufacturer:	PERCUTANEOU	method use to	approved the
	Evaluator :	Angiomed GmbH	S KIDNEY	drain the	products at
	AD-III	& Co.	DRAINAGE	kidneys, when	Sl. No.1-6
		Medizintechnik		an obstruction	subject to
		KG,	55000010	has blocked the	provision of
		Wachausstrasse 6,	55000030	urinary	updated or
		76227 Karlsruhe,	55000040	passage.	valid LOA
		Germany	55000050		valiu LOA
			55000070		
		FSC Germany	55000080		
		Issue date	55000090		
		22.01.2019	Class C		
			Shelf Life 3 years		
			Rs.50,000/-		
	-do-	Legal	Angiomed	A catherization	MDB
4.		Manufacturer:	PERCUTANEOU	method use to	approved the
	Evaluator :	Angiomed GmbH	S KIDNEY	drain the	products at
	AD-III	& Co.	DRAINAGE	kidneys, when	Sl. No.1-6
		Medizintechnik	~~~~~	an obstruction	subject to
		KG,	55000010	has blocked the	provision of
		Wachausstrasse 6,	55000030	urinary	updated or
		76227 Karlsruhe,	55000040	passage.	valid LOA
		Germany	55000050		vana 2011
		Eg C	55000070		
		FSC Germany	55000080		
		Issue date 22.01.2019	55000090		
		22.01.2019	Class C		
			Shelf Life 3 years		
			Rs.50,000/-		
_	-do-	Legal	BROVIAC ®	BROVIAC®	MDB
5.		Manufacturer:	Central Venous	CENTRAL	approved the
	Evaluator:	Bard Access	Catheter	VENOUS	products at
	AD-III	System, Inc.605	0600520	CATHETERS	Sl. No.1-6
		North 5600	0600540	are designed	subject to
		WestSalt Lake	0600040	for long-term	provision of
		City, UT USA. Manufacturing	Class D	vascular access and for use in	updated or

		Sites: 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	Shelf Life 5 years Rs.50,000/-	patients that lack adequate peripheral venous access.	valid LOA
		FSC USA (FDA) Valid till July, Feb.13, 2021			
6.	-do- Evaluator: AD-III	Legal Manufacturer: Bard Access Systems Inc. 605 North 5600 West Salt Lake City Ut, USA 84116 Manufacturing Sites: 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	HICKMAN® CENTRAL VENOUS CATHETER 0600310, 0600320, 0600570, 0600580, 0600600, 0600620, 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. Thety are designed for the administration of I.V fluids parenteral.	MDB approved the products at Sl. No.1-6 subject to provision of updated or valid LOA

	M/s SES	Legal	MAGMA	Drug eluting	Approved
7.	Associates, 148-	Manufacturer/	Rapamycin-Eluting	Coronary Stent	
	Ejaz Park Model	Manufacturing	Coronary Stent	System	
	Town Link	Site:	System		
	Road, Lahore	M/s QualiMed			
	(ELI-00041)	Innovative	Class D		
		Medizinproduket GmbH,	Shelf Life: 18		
		BoschstraBe 16	months		
		D-21423 Winsen, Germany	Fee: 50,000/-		
		(FSC Germany Issuance Date 13-08-2013)			

17. <u>DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

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

		55432, USA Manufacturing Site: 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-MP 6250VI-MP 6250VI-AM 6250VI-AM 6250VI-AM 6250VI-AM 6250VI-BPX 6250VI-BPX 6250VI-BPX	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) Evaluator: AD-III	Legal Manufacturer: Nova biomedical 200 Prospect Street Waltham. MA 02454. USA. (FSC valid15-03- 2024)	Stat Sensor Xpress Creatinine Meter System 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 Sizes & codes 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 Needle shape: Round bodied, straight, cutting, reverse, taper cutting, Needle curvature: 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

	-do-	M/s Shandong	RTMED	Polyglactin	Approved
5.		Haidike Medical	Polyglactin	Absorbable	rr · · · ·
	Evaluator:	Products Co., Ltd.	Absorbable	surgical sutures	
	AD-III	88 meters west of	surgical sutures	(PGLA)	
		Tainfu Road,	(PGLA)	are intended for	
		Dongcheng office	Class-D	use in general	
		Shan County Heze	Shelf life: 5 years	soft tissue	
		City Shandong	Sizes & codes	closing and/or	
		Province, China	USP 12-0, 11-0,	ligation; in	
		FSC China	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0,	particular in general	
		Dated: 27.02.2022	2-0, 0, 1, 2, 3, 4, 5	surgery,	
		Reference country	Needle shape:	gastrointestinal	
		FSC Spain	Round bodied,	surgery,	
		issuance 16-03-	straight, cutting,	gynecology,	
		2020	reverse, taper	obstetrics,	
			cutting,	urology,	
			Needle curvature:	ophthalmic	
			½ circle, 3/8 circle,	surgery	
			straight		
_	M/s. Iqbal and	Legal	Dura lock-C	Dura Lock-C TM	Approved
6.	Company Alfalah manzil	Manufacturer: M/s MEDICAL	(CATHETR LOCK	is indicated for use in	
	Opp. National	COMPONENTS	SOLUTION)	maintaining	
	Police	INC	SOLUTION)	patency Of	
	Foundation	DBA-Medcomp	PFDLC 504	Hemodialysis	
	Street No. E-	1499 DELP	PFDLC 530	Catheters	
	11/4, Islamabad.	DRIVE	PFDLC 546		
	ELI-00117.	HARLEYSVILLE			
		, PA USA 19438	Class B		
	Evaluator :		FEE SUBMITTED		
	AD-III		RS 25,000/-		
		FSC GERMANY	G1 10710 0		
		Issued date 28	Shelf Life 2 years		
		June, 2019			
	M/s Krestacorp,	Legal	Feel Studded	Natural Rubber	Approved
7.	76-C, 3 rd Floor,	Manufacturer/	condoms	Latex Condoms	PP0.00
	Suit No.2,	Manufacturing		is a non-Sterile,	
	Khayaban-e-Jami,	Site:	Natural rubber latex	Single use device	
	Street No.9, DHA Phase 07,	M/s Karex Industries SDN	Male Condoms	made of natural rubber latex,	
	Karachi	BHD PTD. 7906 &	Class C	lubricated with	
		7907 Taman Pontian	Shelf Life: 5 Years	silicone oil. It is	
	Evaluator:	Jaya, Bt. 34, Jalan		Packed in a	
	AD-III	Johor, 82000,	Sizes & Codes:	rolled-up form in	
		Pontian Johor DarulTakzim,	P53D	an individual heretically sealed	
		Malaysia	Rs.50,000	square foil sachet	
				comprises of	
		(FSC Malaysia		polyester/	
		Valid Till		aluminum/	
		13-02-2021)		Polyethylene/ LDDPE. Foiled	
		FSC reference		LDDPE. Folled	

		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) Evaluator: AD-IV [759-P]	Manufacturer: M/s. USM Healthcare Medical Devices Factory JSC Lot I-4b-1.3, N3 Street, Saigon Hitech 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 Certficate 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 Desciption	Decesion of MDB
	M/s Zenith	Legal	PERFECT	Disposable Vinyl	Approved
1.	International,	Manufacturer	(Disposable Vinyl	Examination	subject to
	Room No.	M/s Blue Sail	Examination	Gloves, Non-	provision valid
	104, Tahir	Medical Co., Ltd	Gloves, Non-	Sterile, Powdered.	ISO.13485
	Plaza A/20	No, 21 Qingtian	Sterile,		Certificate.
	Block 7&8	Road, Qilu	Powdered).		

	K.C.H.S.U	Chemical	Class-A		
	Karachi.	Industrial Park,	Shelf Life: 60		
	ELI: 00090.	Zibo City	months		
	LLI. 00050.	Shandong	months		
		Province, China	Rs. 5,000/-		
		FSC: China	145. 2,000/		
	-do-	Legal	BLUE SAIL+	Disposable Nitrile	Approved
2.		Manufacturer	Disposable Nitrile	Examination	subject to
		M/s Blue Sail	Examination	Gloves, Non-	provision valid
		Medical Co., Ltd	Gloves, Non-	Sterile, Powder	ISO.13485
		No, 21 Qingtian	Sterile, Powder	Free.	Certificate.
		Road, Qilu	Free		
		Chemical	Class-A		
		Industrial Park,	Shelf Life: 60		
		Zibo City	months.		
		Shandong			
		Province, China			
		FSC: China			
	-do-	Manufacturer:	PERFECT FINE,	Disposable Suction	Approved
3.		M/s Hospital &	Disposable	Catheter	subject to
		Hemocare	Suction Catheter.		inspection of
		Medical Devices	Shelf Life: 60		manufacturer
		Co., Ltd., No. 188	months.		abroad and
		East of Jingwu	Class-B.		provision valid
		Road, West Side,			ISO.13485 &
		Ye Ya Science			Full QA
		and Technology			Certificate.
		Park, Jianhu, Jiangsu, China			
	M/s. Freesia		PROFEEL	Profeel ® NR Latex	A
4.	Enterprises	Legal Manufacturer:	powder free latex	Surgical Gloves	Approved subject to
-	Address: First	Manufacturer.	surgical gloves	(powder free and	inspection of
	Floor,104	M/s. WRP Asia	sterile.	sterile) is intended	manufacturer
	Dawn Plaza,	Pacific Sdn.Bhd	sterife.	for surgical work	abroad and
	Bank Road,	Lot 1, Jalan 3,	Class: B	and for single use	provision of
	saddar,	Kawasan		only.	original slip of
	Rawalpindi	Perusahaan	Shelf Life: 03		fee deposited
	•	Bandar Baru Salak	Years		attested by
		Tinggi, 43900			Director of B&A,
		Sepang, Selangor			DRAP.
		Darul Ehsan,			
		Malaysia.			
l _	-do-	Legal	COMFIT-NR	Comfit NR Latex	Approved
5.		Manufacturer:	Latex Surgical	Surgical Gloves	subject to
			gloves powdered	(powered and	inspection of
		M/s. WRP Asia	sterile	sterile) is intended	manufacturer
		Pacific Sdn.Bhd,	CI D	for surgical work	abroad and
		Lot 1, Jalan 3,	Class: B	and for single use	provision of
		Kawasan	Chair Tir. 00	only. The surface	original slip of
		Perusahaan	Shelf Life: 03	powder should be	fee deposited
		Bandar Baru Salak	years	removed by a	attested by
	1	Tinggi, 43900	I	sterile prior to	Director of B&A,

6.	-do-	Sepang, Selangor Darul Ehsan, Malaysia Legal Manufacturer: M/s. WRP Asia Pacific Sdn.Bhd Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia	COMFIT PREMIUM-NR latex surgical gloves powdered sterile Class: B Shelf Life: 03 Years	undertaking operation procedures in order to minimize the risk of any adverse tissue reaction. 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.	Approved 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	NASAL OXYGENCANN ULA (Pediatric/ Adult) Class-B	Nasal Oxygen Cannula Pediatric/Adult. products in the group as a 'family' should be applied separately.	Approved 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-	Legal Manufacturer: M/s. PLASTI- MED Deri OSB Mahallesi Yn Sanayi Cad. No: 13 Tuzla/Istanbul Turkey. FSC Turkey Date of Issue: 3 rd April,2017	NEBULIZER SET 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.	
9.	-do-	Legal Manufacturer: Lot 1, Jalan 3, Kawasan Perusahaan bandar Baru Salak Tinggi, 43900 Sepang,	PROFEEL DHDTM EXTRA 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	Approved subject to inspection of manufacturer abroad and provision of original slip of

10.	-do-	Selangor Darul Ehsan Malaysia FSC: Malaysia Date of issue 21st March,2011 Legal Manufacturer: M/s. WRP Asia	PROFEEL double gloving system latex powder free latex surgical	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). Profeel double gloving system latex powder free latex surgical	fee deposited attested by Director of B&A, Approved subject to inspection of manufacturer
		Pacific Sdn.Bhd Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia	gloves sterile. Class: B Shelf Life: 03 Years	latex surgical gloves sterile	manufacturer abroad and provision of original slip of fee deposited attested by Director of B&A,
11.	-do-	Legal Manufacturer: Deri OSB Mahallesi Yn Sanayi Cad No. 13 Tuzla/Istanbul Turkey. FSC: Turkey Date of issue: 03.04.2017	OXYGEN MASK. Adult/Pediatric Class-B	It is used to give oxygen to treat the potentially harmful and deadly effect of hypoxemia	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	Legal Manufacturer: Hayat Kimya Sanayi A. S (Headquarter) Mahir Iz Card No. 25, 34662 Uskudar/ Istanbul. Factory site: Sepetlipinar Mah.Hayat	EVONY 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)	Approved subject to provision of Full QA Certificate.

	Т	T	T	Т	
		Cad.No.!			
	ELI: 00605.	Basiskele.Kocaeli			
		FSC: Istanbul			
		Date of issue:			
		04-07-2020.			
	M/s 3A Nutra,	Legal	DISPOSABLE	This medical device	Approved.
13.	12-FI, Johan	Manufacture:	MEDICAL Face	covers mouth, nose	
	Town, Lahore	M/s Changzhou	Mask	and chin to prevent	
		Baidelin Health		the transmission of	
	ELI: 00134.	Material Co., Ltd		infectious agents	
		No. 218, Sanhe	Medical Face	amongst people,	
		road Sanhekou	Mask/ 3 ply face	hospital staff and	
		Development	mask	the patients. The	
		Zone Zhenglu		product is meant to	
		Town, Tianning	Class-A	be used by	
		District,		healthcare	
		Changzhou city,	Shelf Life: 3 years	professionals and	
		Jiangsu Province,		the general public	
		China		for their personal	
		FSC: China		protection. This	
		Valid till:		product prevents	
		2021.05.18		acquiring any	
				infection from and	
				prevents the entry	
				of dust and other	
				airborne particles	
				into the mouth and nose of an	
				nose of an individual.	
	M/s A.M	Legal	COVER X®	Cover X ® Surgical	Approved.
14.	Distributors	Manufacturer:	Disposable Drapes	Disposable sterile	PP
	4 th Floor, Plot		and Gowns	surgical drapes are	
	37-C, Bukhari	HENAN Medical		used during surgery	
	Commercial	Technology Co.,	(6307-9090-4818-	to prevent contact	
		Ltd Huayuan	9000)	with unprepared	
	Phase VI,	Road NO, 39,		surfaces and to	
	DHA, Karachi	Jinshui District,	Class-A	maintain the	
		Zhengzhou City,		sterility of	
	ELI: 00248	Henan Province	Shelf Life: 5 years	environmental	
		China		surfaces, equipment	
				and the patient's	
		FSC: China		surroundings.	
				Cover X ® Surgical	
		Valid till:		Disposable Sterile	
		26.07.2021		surgical gowns are	
				worn the scrub suit	
				of the operation	
				team during	
				surgical procedures	
				to maintain a sterile	
				surgical field and	
I				reduce the risk of transmission of	

				pathogens to both patients and staff.	
				patients and starr.	
15.	M/s. AL-Walli Care Concepts 86-Allama Iqbal Road Garhi Shahu Lahore ELI-00386	Legal Manufacture: 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.	NITRILE Powdered Surgical Gloves (Surgical Gloves) Class-B	Surgical Gloves	Approved subject to provision of valid FSC of USFDA and shelf life Firm shall apply separately for powder free gloves.
16.	-do-	Legal Manufacture: 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.	LATEX Powdered Surgical Gloves (Surgical Glove) Class- B	Surgical Gloves.	Approved 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	Legal Manufacturer Mexpo International Inc. 2828 Faber Street, Union City CA 94587, USA Production Facility: TG Medical Sdn.	LATEX SURGICAL Powder Free Gloves Class-B Shelf Life 5 years	Latex Surgical Powder Free	Approved subject to submission of EPSPs.

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

		6070, Jalan Haji Abdul Manan 6 th Miles off Jalan Meru,41050 Klang, Selangor, Darul Ehsan Malaysia			
20.	-do-	Legal Manufacturer: M/s. Supermax Glove Manufacturing Sdn Bhd Manufacturing Site: 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 Lot 42, Putra Industrial Park Bukit Rahman Putra 47000 Sungai Buloh Selangor Darul Ehsan Malaysia Production Site: Maxter Glove Manufacturing Sdn. Bhd Lot 6070, Jalan Haji Abdul Manan 6th Miles off Jalan Meru,41050 Klang, Selangor, Darul Ehsan Malaysia	SUPERMAX- Sterile LATEX SURGICAL 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.	Approved subject to provision of original agency agreement, DoC and EPSP and shelf life
21.	M/s A.M Distributors; 4 th Floor, Plot 37-C, Bukhari Commercial Area Lane & Phase VI, DHA, Karachi. ELI: 00248.	Legal Manufacturer: HENAN Medical Technology Co., Ltd Huayuan Road NO, 39, Jinshui District, Zhengzhou City, Henan Province China	COVER-X® 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	Approved.

		FSC: China		field and reduce the risk of	
				transmission of pathogens to both patients and staff.	
		Valid till: 26.07.2021			
22.	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:	mask. (Disposable Medical 3-ply face mask) Class-A.	Face mask	Approved subject to provision of justifiable stability study data for claimed shelf life.
23.	M/s United Healthcare, Plot No. 330, 2 nd Floor, DMCH, Bahadurabad, Karachi.	2021.05.18 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.)	• Deferred; firm asked to provide theoriginal 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	• Deferred; 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.
25.	M/s Batla Impex, Shop. 40, Namco Centre, Cambell Street, Karachi2656-S- (MD)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co. Ltd. No. 118 Huaguang Road, Zhangdian District Zibo 255000 Shandong China.	NEW GOLDEN Sterile Nebulizer Mask. Class B	Sterile Nebulizer Mask	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.	NEW GOLDEN 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

	M/s. 4A	Legal	EMEDICAL	A laryngeal mask	Approved
27.	International	Manufacturer:	Laryngeal Mask	airway is a device	subject to
	Plot 7, Street	M/s. Excellentcare	Airway	inserted into the	provision of
	11, Lawyers	Medical	Anway	patient's trachea	justifiable
	Society,	(Huizhou) Ltd	(Laryngeal Mask	through the mouth	stability study
	Chaklala,	Manufacturer	Airways)	to maintain an open	data and FSC of
	Rawalpindi	Site: Shatou	All ways)	airway. It is used to	country of origin.
	Kawaipiliui		Class. D	_	Country of origin.
	(ELL 00000)		Class: B	assist the delivery	
	(ELI-00099)	Yuanzhou Town,	C1 1C1 'C 07	of anaesthetic gases	
	944-P-(MD)	<u> </u>	Shelf Life: 05 years	or air to and from	
		Huizhou,	D 25 000/	the patient.	
		Guangdong, China,	Rs. 25,000/-		
	_	516123.			
	-do-	Legal	EMEDICAL Gel	A gel laryngeal	Approved
28.		Manufacturer:	Laryngeal Mask	mask airway is a	subject to
		M/s. Excellentcare	Airway	device inserted into	provision of
		Medical		the patient's trachea	justifiable
		(Huizhou) Ltd	Class: B	through the mouth	stability study
		Manufacturer	Shelf Life: 05	to maintain an open	data and FSC of
		Site: Shatou	years	airway. It is used to	country of origin.
		Industrial Zone,		assist the delivery	
		Yuanzhou Town,	Rs.25,000/-	of anaesthetic gases	
		Boluo County,		or air to and from	
		Huizhou,		the patient.	
		Guangdong, China,			
		516123.			
	-do-	Legal	EMEDICAL	Oxygen mask is a	Approved
29.		Manufacturer:	Oxygen Mask.	device clinically	subject to
		M/s. Excellentcare		used for supporting	provision of
		Medical	Class: B	oxygen or other	justifiable
		(Huizhou) Ltd	Shelf Life: 05	medical gas for	stability study
		Manufacturer	years	patients. It is used	data and FSC of
		Site: Shatou		to cover patient's	country of origin.
		Industrial Zone,	Rs.25,000/-	face and support	, ,
		Yuanzhou Town,	,	oxygen and gas by	
		Boluo County,		oxygen tube.	
		Huizhou,			
		Guangdong,China,			
		516123.			
	-do-	Legal	EMEDICAL	Nasal cannulas are	Approved
30.		Manufacturer:	Nasal Cannula	devices clinically	subject to
		M/s. Excellentcare		used for delivering	provision of
		Medical		oxygen or other	justifiable
		(Huizhou) Ltd		medical gas for	stability study
		Manufacturer	Class: B	patients. It is used	data and FSC of
		Site: Shatou		to insert into the	country of origin.
		Industrial Zone,	Shelf Life: 05	patient's nose and	Journal of Origini.
		Yuanzhou Town,	years end of	deliver oxygen or	
		Boluo County,	Jeans	other medical gas	
		Huizhou,	Rs.25,000/-	by oxygen tube.	
		Guangdong, China,	13.23,000/-	of oxygen tube.	
		516123.			
		310123.			
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31.	-do-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	EMEDICAL HME for Tracheostomy Patient. 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	Approved subject to provision of justifiable stability study data and FSC of country of origin.
32.	-do-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123.	EMEDICAL Nebulizer. Class: B Shelf Life: 05 years Rs.25,000/-	Nebulizer is used to deliver aerosolized medication to the lungs	Approved subject to provision of justifiable stability study data and FSC of country of origin.
33.	-do-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	EMEDICAL Breathing Circuit Non-Invasive Disposable Class: B Shelf Life: 05 years. Rs.25,000/-	Breathing Circuit is used to transfer gas between the patient and the anesthesia machine, CPAP machine, BiPAP machine and the ventilator	Approved subject to provision of justifiable stability study data and FSC of country of origin.
34.	-do-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou,	EMEDICAL Suction Tube. 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.	Approved subject to provision of justifiable stability study data and FSC of country of origin.

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

39.	-do-	Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong, China, 516123. Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County,	Shelf Life: 05 years Rs.25,000/- EMEDICAL Breathing Circuit Expandable Disposable Class: B Shelf Life: 05 years.	connectors, Machine end connectors Breathing Circuit is used to transfer gas between the patient and the anesthesia machine and the ventilator	Approved subject to provision of justifiable stability study data and FSC of country of origin.
40.	-do-	Huizhou, Guangdong,China, 516123. Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	Rs.25,000/- EMEDICAL Breathing System Filter Antibacterial/viral 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.	Approved subject to provision of justifiable stability study data and FSC of country of origin.
41.	-do-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	EMEDICAL HME& Antibacterial/Vir al Filter 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.	Approved subject to provision of justifiable stability study data and FSC of country of origin.
42.	-do-	Legal Manufacturer: M/s. Excellentcare Medical	EMEDICAL Breathing Circuit Disposable.	Breathing Circuit is used to transfer gas between the patient and the	Approved subject to provision of justifiable

		(Huizhou) Ltd Manufacturer Site: 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-	Legal Manufacturer: M/s. Excellentcare Medical (Huizhou) Ltd Manufacturer Site: Shatou Industrial Zone, Yuanzhou Town, Boluo County, Huizhou, Guangdong,China, 516123.	Class-B Shelf Life: 5 years	Anesthetic Face Mask	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).

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

		country of
		origin, signed
		& 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
		importer.
		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/org
		anization has
		issued this
		certificate
		and under
		what
		mandate?
		ICO 12407
		ISO 13485
		and Full QA
		certificate is
		not notarized.
		Provide
		notarized
		certificates

	1			<u> </u>	
					Provide Essential Principles of Safety and Performance of applied product
					Stability studies not provided. Provide shelf life studies supporting claimed shelf life of 3 years
					Provide MRP for the applied device
					Provide details of manufacturin g of the applied device
					Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3rd meeting.
					Provide label of the applied device
2.	-do-	Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH	Triacid-N (Disinfectant) Class C	Aldehyde-free concentrate for the manual disinfection of	Deferred for provision of following documents:

Carl-Friedrich- Gauss-Strabe 7, 50259, Pulheim, Germany issued on 10-11- 2016 Size: 11., 5L. Fee submitted: Rs.50,000/- Rs.50,000/- The LOA/Agency agreement. The LOA/Agency agreement shall be original, notarized from the country of origin, signed & stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive e authorization is given to importer. The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language.	 				
Size: IL., SL. FSC Germany issued on 10-11- 2016 Fee submitted: Rs.50,000/- Rs.50,000/- The LOA/Agency agreement. The LOA/Agency agreement. The LOA/Agency agreement. The LOA/Agency agreement. Aving validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which Sole/Exclusive e authorization is given to importer. The issuing Authority of the provided Free Sale Certificate (FSC) of Germany is mentioned in German Language.			G1 16716 65		
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			Authority/org
			anization has issued this
			certificate
			and under
			what
			mandate?
			ISO 13485
			and Full QA
			certificate is
			not notarized.
			Provide notarized
			certificates
			certificates
			Product
			details
			provided in
			German
			language.
			Provide English
			English translation of
			the document
			the document
			Provide
			Essential
			Principles of
			Safety and
			Performance of applied
			of applied product
			product
			Stability
			studies not
			provided.
			Provide shelf
			life studies
			supporting
			claimed shelf life of 3 years
			ine of 5 years
			Provide MRP
			for the
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			g of the
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					applied device Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3rd meeting. Provide label of the applied device
3.	-do-	Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich- Gauss-Strabe 7, 50259, Pulheim, Germany FSC Germany issued on 10-11- 2016	Biguacid-S (Disinfectant) Class B Shelf Life: 05 Years Size: 1L, 5L, 10L Fee submitted: Rs.50,000/-	Aldehyde-free Surface disinfectant for medical devices Composition: 100 g contain: 17.5 g Didecyldimeth yl ammonium chloride 4 g polyhexanide	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 & 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. 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/org anization has issued this certificate and under what mandate? ISO 13485 and Full QA certificate is not notarized. Provide Provide notarized certificates Provide Essential Principles of Safety and Performance of applied product Stability studies not provided.			
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			Stability
provided.			
		 	 provided.

					Provide shelf life studies supporting claimed shelf life of 5 years Provide MRP for the applied device Provide details of manufacturin g of the applied device Credentials not provided. Provide credentials of manufacturer abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3rd meeting. Provide label of the applied device
4.	-do-	Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich- Gauss-Strabe 7, 50259, Pulheim, Germany FSC Germany issued on 10-11- 2016	Antiseptica Combi Instruments-N (Disinfectant) Class C Shelf Life: 03 Years Size: 1L, 5L Rs.50,000/-	For the manual disinfection of surgical instruments and laboratory equipment Composition: 100 g contain: 8 g Glutaraldehyd e 5.75 g Formacetale	Deferred for provision of following documents: Letter of Authorization (LOA) expired. Provide valid LOA/agency agreement. The LOA/Agency agreement shall be original,

ī	T	T	- , , ,
			notarized
			from the
			country of
			origin, signed
			& 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
			importer.
			TT1 : :
			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/org
			anization has
			issued this
			certificate
			and under
			what
			mandate?
			ISO 13485
			and Full QA
			certificate is
			not notarized.
			Provide
 	<u> </u>	 	1101100

		notarized
		certificates
		certificates
		Provide
		Essential
		Principles of
		Safety and
		Performance
		of applied
		product
		F
		Stability
		studies not
		provided.
		Provide shelf
		life studies
		supporting
		claimed shelf
		life of 3 years
		Provide MRP
		for the
		applied
		device
		D
		Provide details of
		manufacturin
		g of the applied
		device
		device
		Credentials
		not provided.
		Provide
		credentials of
		manufacturer
		abroad (duly
		notarized
		from country
		of origin) on
		format
		approved by
		Medical
		Devices
		Board in its
		3 rd meeting.
		Provide label
		of the applied
		device

	J.	Lagal	Flexicare Adult	Cin ala usa	Deferred for
5.	-do-	Legal		Single use	
٥.		Manufacturer:	Breathing	Adult	provision of
		M/s Flexicare	Circuit	Breathing	following
		Medical Limited,	~	Circuit	documents:
		Cynon Valley	Codes & Sizes:		Letter of
		Business Park,	Not CLEAR		Authorization
		Mountain Ash,			(LOA) is not
		CF45 4ER, UK	Class B		NOTARIZE
					D. Provide
		Manufacturing	Shelf Life: 05		the
		Site:	Years (NOT		LOA/Agency
		M/s Flexicare	COMPLETE)		agreement
		Medical	,		which shall
		(Dongguan)	Fee submitted:		be original,
		Limited, No. B-	Rs.25,000/-		notarized
		15, District I, Xi	,		from the
		Cheng Industrial			country of
		Zone, Hengli			origin, signed
		Town, Dongguan			& stamped,
		City, Guangdong			having
		Province, 523460,			validity,
		PR China.			names and
		Tre China.			addresses of
		FSC UK Issuance			both
		Date			manufacturer
		(15-02-2019)			and importer
		(13-02-2017)			and importer
					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

		nrodust: -
		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
		manufacturin
		g 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
		aiso
		ISO13485
		(UK)
		expired.
		Provide valid
		certificate
		Highlight the
		product
		codes
		required on
		this
		application
		on Letter of
		Authorization
		, Free sale
		certificate
		and
		Declaration
		of G. f. :
		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.
					Provide MRP for the
					applied device
					Provide Instructions
					for use (IFU) for the
					applied device
6.	-do-	Legal Manufacturer:	Flexicare Paediatric	Single use Paediatric	Deferred for provision of
		M/s Flexicare Medical Limited,	Breathing Circuit	Breathing Circuit	following documents:
		Cynon Valley Business Park,	Codes & Sizes:		Letter of Authorization
		Mountain Ash,	Not CLEAR		(LOA) is not

CF45 4ER, UK		NOTARIZE
CF43 4ER, UK	Clara D	
3.5	Class B	D. Provide
Manufacturing	G1 107 12	the
Site:	Shelf Life: 05	LOA/Agency
M/s Flexicare	Years (NOT	agreement
Medical	COMPLETE)	which shall
(Dongguan)		be original,
Limited, No. B-	Fee submitted:	notarized
15, District I, Xi	Rs.25,000/-	from the
Cheng Industrial		country of
Zone, Hengli		origin, signed
Town, Dongguan		& stamped,
City, Guangdong		having
Province, 523460,		validity,
PR China.		names and
		addresses of
FSC UK Issuance		both
Date		manufacturer
(15-02-2019)		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
		Paediatric
		Breathing
		Circuit is
		being
		manufactured
		in China site
		in Cillia site

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 product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also ISO13485 (UK) expired. Provide valid certificate 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	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 product is manufactured in China then provide valid and notarized ISO13485 and Full QA certificate also ISO13485 (UK) expired. Provide valid certificate Highlight the product codes required on this application on Letter of Authorization , Free sale certificate and Declaration of Conformity, Justify how can the			1	or UK site or
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	be grouped together on one application				
	be grouped together on one application				applied codes
be grouped	together on one application				
	one application				
	application				-
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					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.
					Provide MRP
					for the
					applied
					device
					Provide
					Instructions
					for use (IFU)
					for the
					applied
					device
	-do-	Legal	Flexicare	Oxygen and	Deferred for
7.		Manufacturer:	Oxygen and	Aerosol	provision of
		M/s Flexicare	Aerosol Therapy	Therapy	following
		Medical Limited,	Devices	Devices	documents:
		Cynon Valley			Multiple
		Business Park,	Codes & Sizes:		products
		Mountain Ash,	Not CLEAR		cannot be
		CF45 4ER, UK	Class P		applied on
		Manufacturina	Class B		one
		Manufacturing Site:	Shelf Life: 05		application. Clearly state
		M/s Flexicare	Years (NOT		the one
		Medical	COMPLETE)		product that
		(Dongguan)			is required on
	1	(Doingguail)	1	<u>I</u>	15 required oil

T : 1, 1 NT TO	T 1 10 1	41.1
Limited, No. B-	Fee submitted:	this
15, District I, Xi	Rs.25,000/-	application
Cheng Industrial		and then
Zone, Hengli		highlight the
Town, Dongguan		product
		codes of that
City, Guangdong		
Province, 523460,		product on
PR China.		Letter of
		Authorization
FSC UK Issuance		, Free sale
Date		certificate
(15-02-2019)		and
(15 02 201))		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.
		Letter of
		Authorization
		(LOA) is not
		NOTARIZE
		D. Provide
		the
		LOA/Agency

				o aroom or t
				agreement
				which shall
				be original,
				notarized
				from the
				country of
				origin, signed
				& 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
				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
				Oxygen and
				Aerosol
				Therapy
				Devices is
				being
				manufactured
				in China site
				or UK site or
				both sites?
				and also who
L	 <u> </u>	<u> </u>	<u> </u>	and and will

				T	2 - 41 - 1 1
					is the legal
					manufacturer
					of the applied
					product? Then provide
					•
					complete details of
					manufacturin
					g 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
					aiso
					ISO13485
					(UK)
					expired.
					Provide valid
					certificate
					Provide MRP
					for the
					applied
					device
					Provide
					Instructions
					for use (IFU)
					for the
					applied
					device
					30,100
	-do-	Legal	Flexicare	Anaesthesia	Deferred for
8.		Manufacturer:	Anaesthesia	Components	provision of
		M/s Flexicare	Components		following
		Medical Limited,			documents:
		Cynon Valley	Codes & Sizes:		Letter of
		Business Park,	Not CLEAR		Authorization
		Mountain Ash,	GI 5		(LOA) is not
		CF45 4ER, UK	Class B		NOTARIZE
		N.T. C	01 101 10 07		D. Provide
		Manufacturing	Shelf Life: 05		the
		Site:	Years (NOT		LOA/Agency
		M/s Flexicare	COMPLETE)		agreement
		Medical (Dongguan)	Fee submitted:		which shall be original,
1					

		D 27 0001	<u> </u>	
	Limited, No. B-	Rs.25,000/-		notarized
	15, District I, Xi			from the
	Cheng Industrial			country of
	Zone, Hengli			origin, signed
	Town, Dongguan			& stamped,
	City, Guangdong			having
	Drawing 522460			
	Province, 523460,			validity,
	PR China.			names and
				addresses of
	FSC UK Issuance			both
	Date			manufacturer
	(15-02-2019)			and importer
	(13 02 201))			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
				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?
<u> </u>		<u> </u>	I .	

Then provide complete details of manufacturin g 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 ISO13485 (UK) expired. Provide valid certificate also 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	T		1	TD1 · ·
details of manufacturin g 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 ISO13485 (UK) expired. Provide valid certificate 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				
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		the codes
		applied.
		Clearly state
		the
		similarities
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		differences
		among the different
		codes applied
		and then
		provide
		stability
		studies for
		the applied
		codes
		supporting
		the claimed
		shelf life.
		Provide MRP
		for the
		applied
		device
		Provide
		Instructions
		for use (IFU)
		for the
		applied device
		device
	Anaesthesia	Deferred for
	Face Mask	provision of
M/s Flexicare Face Mask		following
Medical Limited,		documents:
Cynon Valley Codes & Sizes: Business Park, Not CLEAR		Letter of Authorization
Mountain Ash,		(LOA) is not
CF45 4ER, UK Class B		NOTARIZE
		D. Provide
Manufacturing Shelf Life: 05		the
Site: Years (NOT		LOA/Agency
M/s Flexicare COMPLETE)		agreement
Medical (Dongguan) Fee submitted:		which shall
(Dongguan) Fee submitted: Limited, No. B- Rs.25,000/-		be original, notarized
15, District I, Xi		from the
Cheng Industrial		country of
Zone, Hengli		origin, signed
Town, Dongguan		& stamped,
City, Guangdong		having
Province, 523460,		validity,

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	nd importer
	nd having
	name or
	ategory of
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	levices for
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	uthorization
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	mporter.
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	Manufacturin
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	ot clear
	rom Free
	Sale
	Certificate.
	Clarification
	s required
	rom
	MANUFAC
	TURER that
	he particular
	pplied
	product i.e
	Anaesthesia
	Face Maskis
	eing
	nanufactured
	n China site
	or UK site or
	ooth sites?
	nd also who
	s the legal
	nanufacturer
	of the applied
	product?
	Then provide
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	letails of
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	ests of the
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			product is
			manufactured
			in China then
			provide valid
			and notarized
			ISO13485
			and Full QA
			certificate
			also
			ISO13485
			(UK)
			expired.
			Provide valid
			certificate
			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 opposition
			by supporting
			your claim
			with
			brochure,
			pictures as
			well as by
			providing all
			the labels of
			the codes
			applied.
<u> </u>	1		applica.

					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. Provide MRP
					for the applied device
					Instructions for use (IFU) for the applied device
10.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.	Flexicare Catheter Mount Codes & Sizes: Not CLEAR Class B Shelf Life: 05 Years (NOT COMPLETE) Fee submitted: Rs.25,000/-	Single-use Catheter Mount	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 & stamped, having validity, names and addresses of

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	FSC UK Issuance		both
	Date		manufacturer
	(15-02-2019)		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
			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
			manufacturin
			g and QC
			tests of the
			applied
			device. If the
			product is
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T		
		manufactured
		in China then
		provide valid
		and notarized
		ISO13485
		and Full QA
		certificate
		also
		ISO13485
		(UK)
		expired.
		Provide valid
		certificate
		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
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					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.
					shell life.
					Provide MRP
					for the
					applied
					device
					Provide
					Instructions
					for use (IFU)
					for the
					applied
					device
	-do-	Legal	Flexicare	Sterile, single	Deferred for
11.		Manufacturer:	Endotracheal	use	provision of
		M/s Flexicare	Tube	endotracheal	following
		Medical Limited,		tube	documents:
		Cynon Valley	Codes & Sizes:		Letter of
		Business Park,	Not CLEAR		Authorization
		Mountain Ash,			(LOA) is not
		CF45 4ER, UK	Class B		NOTARIZE
					D. Provide
		Manufacturing	Shelf Life: 05		the
		Site:	Years (NOT		LOA/Agency
		M/s Flexicare	COMPLETE)		agreement
		Medical			which shall
		(Dongguan)	Fee submitted:		be original,
		Limited, No. B-	Rs.25,000/-		notarized
		15, District I, Xi			from the
		Cheng Industrial			country of
		Zone, Hengli			origin, signed
-					

T T		Т	
	Town, Dongguan		& stamped,
	City, Guangdong		having
	Province, 523460,		validity,
	PR China.		names and
			addresses of
	FSC UK Issuance		both
	Date		manufacturer
	(15-02-2019)		and importer
			and having
			name or
			category of
			medical
			devices for
			which
			Sole/Exclusiv
			e
			authorization
			is given to
			importer.
			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
			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
			manufacturin
			g and QC
			tests of the
			coss of the

			applied
			applied
			device
			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.
			Rougie chall
<u> </u>	<u> </u>		Bougie shall

					be applied n separate application Provide MRP for the applied device Provide Instructions for use (IFU) for the applied device
12.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date (15-02-2019)	Flexicare LarySeal laryngeal mask airways Codes & Sizes: Not CLEAR Class B Shelf Life: 05 Years (NOT COMPLETE) Fee submitted: Rs.25,000/-	LarySeal laryngeal mask airways	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 & 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

		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
		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
		manufacturin
		g 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
		one is expired.
		слриси.
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				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

					shelf life.
					Provide MRP for the applied device Provide Instructions for use (IFU) for the applied device
13.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date (15-02-2019)	Flexicare Breathing Filters Codes & Sizes: Not CLEAR Class B Shelf Life: 05 Years (NOT COMPLETE) Fee submitted: Rs.25,000/-	Non-sterile, single-use breathing filters	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 & 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. 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
			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
			manufacturin
			g 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
			aiso
			TT: -1-1: -11
			Highlight the
			product
			codes
			required on
			this
			application
			on Letter of
			Authorization
			, Free sale
1	L	<u> </u>	 ,

			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.
			SHOII IIIC.
			Provide MRP
			for the
			applied
			device
			Provide
			Instructions
			for use (IFU)
			for the
			applied
 	 		device
		•	

14. M/s Nisa Impex (Pvt) Ltd, Plot no. 13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA-II G.T. Road Islamabad. ELI-00064	Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7 th Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China. FSC INCOMPLETE	Nisa Medical Protective Face Mask Codes: FSC incomplete Class-A (firm applied as class B) Shelf life: 2 years (studies not provided) Fee submitted: Rs. 5,000/-	Used for filtering particles, blocking droplets, blood, bodily fluids and secretions in the air under the medical working environment.	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 manufacturin g 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
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		ı	. ,
			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
			& 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
			importer.
			•
			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

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			authorities of
			the country
			of origin duly
			attested by
			Embassy of
			Pakistan in
			that country
			for the
			applied
			product
			F
			Provided
			label of the
			product
			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
			Manufacturin
			g site is not
			mentioned on
			form. Clearly state the
			name and
			address of the
			site where the
			masks are
			manufactured

15.	-do-	Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7 th Group, Wanjie	Nisa Surgical Face Mask Codes: FSC not provided Class-A (firm	For clinical medical personnel to wear in the process of traumatic operation to	Deferred for provision of following documents: The product is a class-A medical
		Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China. FSC NOT PROVIDED	Class-A (firm applied as class B) Shelf life: 3 years (studies not provided) Fee submitted: Rs. 5,000/-	operation to provide protection for the patients who are being treated and medical staff and prevent spread sored of blood, body fluids and splashes.	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
					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 QA certificate, Essential principles of safety and

		performance,
		Declaration
		of conformity
		etc.
		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
		& 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
		importer.
		F 1
		Free sale
		certificate not
		provided.
		Submit
		original,
		valid, Free
		Sale
		certificate
		from the
		health
		authorities of

the country of origin du attested by Embassy of Pakistan in	ıly
attested by Embassy of	
Embassy of	
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that country	J
for the	<i>'</i>
applied	
product	
Whether the	e
product is	
available or	ı
free sale in	
reference	
countries	
provided in	
rule 67 of	
MDR, 2017	7?
Provide	
original val	id
free sale	
certificate	
duly atteste	a
by Embassy	
of Pakistan	•
Provide	
readable	
labels of all	
the codes	
required on	
this	
application	
along with	
description	of
the	
similarities	
and	
differences	
among the	
codes appli	
with picture	es
and brochu	
These code	
shall also be	e
available or	1
Free Sale	
Certificate.	Is
the product	
sterile or no	
If it is steril	
then provid	e

				sterilization validation report of the site
16do-	Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7 th Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China. FSC INCOMPLETE	Nisa Medical Face Mask Codes: FSC incomplete Class-A (firm applied as class B) Shelf life: 3 years (studies not provided) Fee submitted: Rs. 5,000/-	Suitable for health care in normal environment	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 full

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			QA
			certificate,
			Essential
			principles of
			safety and
			performance,
			Declaration
			of conformity
			etc.
			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
			& 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
			importer.
			F
			Original Free
			sale
			certificate is
			not found in
			the dossier
			and reference
 <u> </u>	<u> </u>	<u> </u>	and reference

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 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. Provide readable labels of all the codes required on this application along with description of the similarities and			
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17.	M/s Eastern Medical Care	Manufacturer: ASAP	ASAP Latex Powder Free	Non-sterile, single use,	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. Deferred for provision of following
	(Pvt) Ltd, 7A Block N, Model Town Extension, Lahore ELI-00130	International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia FSC Malaysia valid till 05-06- 2020	Examination Gloves Size: Small, Medium, Large, Extra large, Extra Small, Extra extra large Class: A Shelf life: 3 years Fee submitted: Rs. 5,000/-	powder free, natural rubber latex examination glove	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

18.	-do-	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 Powdered Examination Gloves Size: Small, Medium, Large, Extra large, Extra Small, Extra extra large Class: A Shelf life: 3 years Fee submitted: Rs. 5,000/-	Non-sterile, single use, powdered, natural rubber latex examination glove	available on Free Sale in Ireland? Provide valid, notarized Full QA or production QA certificate Provide EU Declaration of Conformity for the applied product 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
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19.	-do-	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 Lite Nitrile 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, powdered, natural rubber latex examination glove	with same specification that is available on Free Sale in Ireland? Provide valid, notarized Full QA or production QA certificate Provide EU Declaration of Conformity for the applied product 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 product applied is ASAP Lite Nitrile Powder Free Examination Gloves where the documents
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			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
			The product
			ASAP Lite
			Nitrile
			Powder Free
			Examination
			Gloves is not
			Free Sale
			Certificate of
			Ireland.
			The free sale
			certificate
			which is copy
			and not
			Embassy
			attested from
			country of
			origin i.e
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			expired and
			the original
			Embassy
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			not found in

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					Embassy
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					gloves
					namelyASAP
					Latex
					Powdered
					Examination
					Gloves,
					ASAP Latex
					Powder Free
					Examination
					Gloves and
					ASAP Lite
					Nitrile
					Powder free
					Examination
					Gloves.
					Provide
					valid,
					notarized
					Full QA or
					production
					QA
					certificate
					Provide EU
					Declaration
					of
					Conformity
					for the
					applied
					device
	M/s Ghazali		Care Face	Not provided	Deferred for
20.	Brothers,	Manufacturer:	Mask	110t provided	provision of
25.	,	M/s Hefei	IVIASK		following
	Ground floor		C1 .		documents:
	& Second	Jingcheng Plastic	Class A		Clarification
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	Karimjee	Ltd, 700 m east	Shelf Life: Not		from
	Building,	of Hong Tu	provided		manufacturer
	North Napier	Avenue and			if the product
	Road, Karachi	Dian Zhong	Fee submitted:		registered for
					registered for

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	(ELI-00240)	Road Junction,	Rs. 5,000/-		use in the
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		Heiei, Cillia			valid,
					Embassy
		FSC UK			attested Free
		Issuance Date			Sale
		(24-06-2019)			Certificate
		(from country
					of origin for
					the applied
					product
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					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
					certificate
					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
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			or for what is
			the intended
			use of the
			device,
			contraindicati
			ons etc?
			Provide
			sample for
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			product
			C1 1
			Clearly state
			if the product
			is sterile or
			not? If it is
			sterile then
			provide
			sterilization
			validation
			report
			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
			aorouu
			Duoral 1 - 11
			Provide the
			QC tests
			performed on
			the mask and
			clearly state
			the standards
			applied on
			the masks
			Provide
			essential
			principles of
			safety and
			performance

					or essential checklist or essential requirements as per EU MDD 93/42/EEC Declaration of Conformity is not signed by responsible personnel. Provide signed and stamped Declaration of conformity on manufacturer letterhead
					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
21.	M/s CCL Pharmaceuticals (Pvt) Ltd, 65 Industrial Estate, Kot Lakhpat, Lahore	Manufacturer: M/s Ningbo Baige Bags Co., Ltd No. 2099 South Ningheng Road, Hengxi Town, Yinzhou District,	Assure Face Mask (Disposable Medical Face Mask) Class: A Shelf Life: 3	Disposable Medical Face Mask	Deferred for provision of following documents: Form 6-A is not stamped. Provide

ELI: 00562	Ningho Theilang	VAare		complete
ELI. 00302	Ningbo, Zhejiang,	years Fac submitted:		
	China	Fee submitted:		form 6-A
		Rs. 5,000/-		with each
				page duly
				signed and
				stamped by
				the CEO or
				responsible
				official and
				provide
				Authority
				letter in case
				of authorized
				official
				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
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				Provide
				original
				Letter of
				Authorization
				or Agency
				agreement
				with
				manufacturer
				abroad, duly
				notarized in
				the country
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of origin. Letter of Authorization or agreement shall be original, signed & 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 Stability studies not provided. Provide complete stability studies supporting the shelf life claim of 3 years. 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			
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will be supplied to Pakistan as claimed for CE marking					
supplied to Pakistan as claimed for CE marking					specifications
Pakistan as claimed for CE marking					
Pakistan as claimed for CE marking					
CE marking					
CE marking					claimed for
of Europe on					
	 <u> </u>	<u> </u>	<u> </u>	<u> </u>	

		Т	
			the letterhead
			signed and
			stamped by
			responsible
			personnel
			•
			Provide MRP
			of the applied
			product
			product
			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.
			or rukistan.
			Provide
			ISO13485
			certificate
			duly
			notarized in
			the country
			of origin
			Provide Full
			Quality
			Assurance
			certificate
			duly
			notarized in
			the country
			of origin
			01 0118111
			Provide
			essential
			principles of
			safety and
			performance
			or essential
			checklist or
			essential
			requirements
			_

					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)	Manufacturer: M/s. Jiangsu Jaysun Glove Co., Ltd No. 199 Jianling Avenue, SuQian economic and technological development zone, Suqian Jiangsu, China FSC China valid till22-7-2021	Safety Examination Vinyl Gloves Size: XS, S, M, L, XL, XXL Class: A Shelf Life: 5 years Fee submitted: Rs. 5000/-	Vinyl gloves are used where high levels of durability and protection is not mandatory, vinyl makes a good multipurpose 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 worm on either hand, and are easy to put on and take off. Non-sterile, single use, vinyl examination glove	Deferred 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

		NTENDED USE It is intended	application? And provide the technical documents
		to use in Medical Examination, hygiene inspection, chemical industry and	(detailed) i.e manufacturin g and QC tests, stability studies of the type required
		pharmacy. These products provide users with	Provide label and brochure of the applied device
		protection when working in these areas	Provide valid, notarized Full QA or production QA certificate
			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
			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 The essential principles provided does not bear product name so it cannot be established that this document is for the applied gloves. Clarify?
23.	M/s Elate CC (Pvt) Ltd., Suite No. 1,2,3, Street No.3, Block No.3, Gulshan- e-Iqbal, Karachi (ELI-00294)	Manufacturer: 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 ICU Ventilators Class B Shelf Life: N/A Fee submitted:Rs.25, 000/-	Ventilator	Deferred for provision of following documents: Ventilator is a class C medical device. Submit differential fee of Rs. 25,000/- Multiple models cannot be applied on application. Clearly state the model of ICU ventilator required on this application. That model shall be

			present on the Free Sale
			Certificate
			and provide
			the detailed
			technical
			documents i.e
			details of
			manufacturin
			g and QC
			tests/perform
			ance report,
			Instruction-
			for-use
			having
			indications,
			contraindicati
			ons etc,
			reference
			manual and
			label of the
			required
			model
			Provide copy
			of
			Establishmen
			t Licence to
			import
			medical
			device
			The Free Sale
			Certificate
			provided is
			not original,
			copy is
			provided.
			Provide
			original
			Embassy
			attested Free
			Sale
			Certificate
			Agency
			agreement is
			not original,
			copy is
			provided.
			Provide
			original
			Agency
		l	

				agreement
				Copies of ISO 13485 and Full QA certificate are provided. Provide these certificates having original notarization
				Provide essential principles of safety and performance/ essential checklist as per EU MDD 93/42/EEC for the required model of ventilator
				Provide Declaration of Conformity for the required model printed on the manufacturer letter head, filled and signed by the responsible person.
				Provide Declaration on stamp paper as specified on Form 7A Credentials not provided. Provide credentials of
	<u> </u>	<u> </u>	<u> </u>	manufacturer

					abroad (duly notarized from country of origin) on format approved by Medical Devices Board in its 3 rd meeting. Provide MRP of the applied device
24.	-do-	Manufacturer: 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 Anesthesia Machine required on this application. That model shall be present on the Free Sale Certificate and provide the detailed technical documents i.e details of manufacturin g and QC tests/perform ance report, Instructionfor-use having indications, contraindicati ons etc, reference manual and

		label of the required model
		Provide copy of Establishmen t Licence to import medical device
		The Free Sale Certificate provided is not original, copy is provided. Provide original Embassy attested Free Sale Certificate
		Agency agreement is not original, copy is provided. Provide original Agency agreement
		Copies of ISO 13485 and Full QA certificate are provided. Provide these certificates having original notarization
		Provide essential principles of safety and performance/ essential checklist as per EU MDD 93/42/EEC

					for the
					required
					model of
					ventilator
					Provide
					Declaration
					of
					Conformity
					for the
					required model
					printed on the
					manufacturer
					letter head,
					filled and
					signed by the
					responsible
					person.
					Provide
					Declaration
					on stamp paper as
					specified on Form 7A
					FORM /A
					Credentials
					not provided.
					Provide
					credentials of
					manufacturer
					abroad (duly
					notarized
					from country
					of origin) on
					format
					approved by Medical
					Devices
					Board in its
					3 rd meeting.
					Provide MRP
					of the applied
					device
	M/s Save on	Legal	HITECARE	Laryngeal	Deferred for
25.	Health Care	Manufacturer:	Laryngeal Mask	Mask.	submission
		Hitec Medical Co.,	Class-B		of justifiable
	Road Lalpul	Ltd No, 703			stability
	Mughalpura	Hengnan RD 1328	Rs.25,000/-		study data,
	Lahore	Minhang district			original and
	ELI: 00027.	201114 Shanghai			valid FSC of
			•	•	

	1150-(P)-	Peoples Republic			country of
	DD(MD)	of China.			origin, notarized agency agreement and ISO- 13485/ GMP
					certificate.
26.	-do-	Legal Manufacturer: Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China.	HITECARE 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, original and valid FSC of country of origin, notarized agency agreement and ISO-13485/ GMP certificate.
27.		Legal Manufacturer: 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	HITECARE (Oxygen Mask) Class-B Shelf Life: 5 years Rs.25,000/-	Oxygen Mask	Deferred for submission of justifiable stability study data, original and valid FSC of country of origin, notarized agency agreement and ISO-13485/ GMP certificate.
28.	-do-	Co., Ltd No, 703, Hengnan Rd Minhang District 201114 Shanghai China Authorized Representative: Shanghai International	HITECARE 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, original and valid FSC of country of origin, notarized agency agreement and ISO-

		20537 Hamburg, Germany FSC: Germany Date of issue: 14 th 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-	Manufacturer: Hitech Medical Co., Ltd No. 703, Hengnan Rd Minhang District 201114 Shanghai China FSC: China Date of Issue: 9 th Jan.2020	HITECARE (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, original and valid FSC of country of origin, notarized agency agreementan d ISO-13485/GMP certificate.
30.	-do-	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	(Reinforced Endotracheal Tube) Class B Shelf Life: 05 years Rs.25,000/-	Reinforced Endotracheal Tube	Deferred for submission of justifiable stability study data, original and valid FSC of country of origin, notarized agency agreement and ISO-13485/ GMP certificate.
31.	-do-	Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China	with yankauer handle) Class-B	Connecting tube with yankauer handle	Deferred for submission of justifiable stability study data, original and valid FSC of country of origin,

		D			<u> </u>
		Date of Issue:			agreement
		10.11.2019			and ISO-
					13485/ GMP
	1	T 1	DIGDOGASTS	D' 11	certificate.
22	-do-	Legal	DISPOSABLE	Disposable	Deferred for
32.		Manufacture:	SURGICAL	Surgical	submission
		M/s Guangzhou	Gown &	Gown &	of justifiable
		Fuzelong Hygiene	Isolation Gown.	Isolation	stability
		Material Co., Ltd	Class- A	Gown	study data,
		12 # Guancum	Shelf Life: 3		original and
		Road Jiangpu	years		valid FSC of
		Street Conghua	D 7 000/		country of
		District	Rs.5,000/-		origin,
		Guangzhou City,			notarized age
		China. FSC: China			ncy
					agreement
		Valid Till: 07-06-			and ISO-
		2020			13485/ GMP
	M/a VI	Local	DDACED	Diana salat	certificate. Deferred for
33.	M/s Vertex	Legal	DRAGER	Disposable	
33.	Medical Pvt Ltd,	Manufacturer	DISPOSABLE Anesthesia	Anesthesia Masks	submission
	70-B-1, Gulberg	M/s Duo samuant		IVIASKS	of justifiable
	III, Lahore	M/s Dragerwerk AG &CO, KGaA	Masks		stability
	ELI: 00150.		COMFORT- STAT		study data,
	ELI: 00130.	Moislinger Allee 53-55 23542	(Disposable		original and valid FSC of
			Anaesthesia		
		Lubeck Germany Manufacturing	Masks)		
		Manufacturing Site:	Codes & Sizes:		origin, notarized
		Dragerwerk	As per FSC:		
		AG&Co. KgaA	Class-B		agency agreement,
		RevalstrBe 1	Shelf Life: See		DoC, Labels,
		23560, Lubeck,	annex-5		justification
		Germany.	ailiex-3		regarding
			Rs.25,000/-		different
		Date of issue:	1.5.25,000/-		sizes and
		15.10.19			ISO-13485/
		13.10.17			GMP
					certificate.
	M/s Endoaid	Legal	RAYSEN Face	Disposable	Deferred for
34.	Biomedica 185-	Manufacturer	Mask	Face mask	submission
	C DHA EME	1, Iunianacturei	TAIMOIT	1 acc mask	of justifiable
	Lahore	Raysen (Tianjin)	Disposable		stability
	Lanoit	Health Care	surgical Mask		study data,
	ELI: 00169.	Product Co. Ltd	20151001 IVIUSK		original and
		No. 3 Huanyuxi	Class: A		valid FSC of
		Road, Tianyu	Shelf Life: 5		country of
		Technology Park,	years		origin,
		Jinghai, Tianjin	, 		notarized
		China	Rs.5,000/-		agency
		FSC: China	, 5 5 5,		agreement,
		Date of Issue:			EPSPs,
		15.05.2021			Labels,
	ı				,

					justification
					regarding
					different
					sizes and
					ISO-13485/
					GMP
					certificate.
	-do-	Legal	FEE- BREATH	Disposable	Deferred for
35.		ManunfacturerMta	Disposable	surgical Mask	submission
		ian Dalu Medical	Nebulizers	C	of justifiable
		Instrument Ltd,	Class: A		stability
		West Part of	Shelf Life: 2		study data,
		Yitianmen street,	years		original and
		HI- Tech Zone,			valid FSC of
		Taian Shahdong	Rs.5,000/-		country of
		ChinaFSC:			origin,
		ChinaDate of			notarized
		Issue: 2021.12.24			agency
					agreement,
					EPSPs,
					Labels,
					justification
					regarding
					different
					sizes and
					ISO-13485/ GMP
					certificate.
	-do-	Legal	RAYSEN	Disposable	Deferred for
36.	-40-	Manunfacturer	Surgical Gown	Surgical	provision of
		Wandinactarer	Surgicul Gown	Gown	details of
		Raysen (Tianjin)	Disposable	Gown	mfg.,
		Health Care	surgical Gown		justifiable
		Product Co. Ltd	8		stability
		No. 3 Huanyuxi	Class: A		study data,
		Road, Tianyu	Shelf Life: 5		original and
		Technology Park,	years		valid agency
		Jinghai, Tianjin	· ·		agreement &
		China	Rs.5,000/-		FSC of
					country of
		FSC: China			origin, EPSP
		Date of Issue:			and labels,
		29.06.2024			complete
					description of
					the key
					functional
					elements, its
					formulation,
					its composition
					composition
					•
					and its functionality.

	M/a Dale Danial	Lagal	MUK	Diancach1-	Dofound for
37.	M/s Pak Punjab	Legal	MHK	Disposable	Deferred for
31.	Cardex Medical	Manufacturer:	MEDIKAL	sterile	provision of
	Systems,	3.7.	Disposable	Surgical	provide MRP,
	Ground Floor,	M/s MHK	Sterile Surgical	Gowns	original and
	210-J/2 Block,	Medikal Tekstill	Gowns		valid free sale
	Johar	Sanayi ve Ticaret			certificate of
	Town,Lahore	Limited Sirketi,	(Disposable		country of
		Karkun Mah.	sterile Surgical		origin duly
	ELI-00174	Hidayet Card. No.	Gowns)		notarized by
		23/1 Oguzelii			the embassy
		Gazlantep,	Class-A		and original
		Turkey.			agency
			Shelf Life: 5		agreement
		FSC: Turkey	years		with all coded
					particulars
			Rs.5,000/-		duly
					notarized by
					the country of
					origin.
	M/s. Sadqain	Legal	FILTA MASK	FILTA	Approved
38.	Healthcare Pvt	Manufacturer:	with medium	MASK	subject to
	Ltd. Rawalpindi.	M/s. Intersurgical	concentration	with medium	provision ov
	ELI-00020.	Limited.	oxygen mask	concentration	original and
		Crane House,	and tubing.	oxygen mask	valid free
		Molly Millars		and tubing	sale
		Lane,	Class: B		certificate of
		wokingha,Berkshi			RRA (UK),
		re,United			original
		Kingdom.			agency
		<i>5</i>			agreement
					and valid
					ISO-13485
					has been
					expired and
					shelf life
	M/s. FM Health	Legal	WELL LEAD	Laryngeal	Deferred for
39.	Care,	Manufacturer:	Laryngeal Mask	Mask Airways	submission
	203, Al-Rehman	M/s Well Lead	Airways.		of justifiable
	Centre Block	Medical Co.,			stability
	7/8 KCHS,	Ltd., C-4 Jinhu	Class: B		study data,
	Shaheed-e-	Industrial Estate,			original and
	Millat Road,	Hualong, Panyu,			valid FSC of
	Karachi.	Guangzhou,			country of
		511434, China			origin,
		511 15 1 , Cillia			notarized
		FSC China Valid			agency
		Till			agreement,
		(09-02-2020)			EPSPs,
		(09-02-2020)			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)	WELL LEAD Oxygen Mask. Class: B	Oxygen Mask	Deferred for submission of justifiable stability study data, original and valid FSC of country of origin, notarized 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)	WELL LEAD Disposable Air Cushion Face Mask.	Disposable Air Cushion Face Mask	Deferred for submission of justifiable stability study data, original and valid FSC of country of origin, notarized agency agreement, EPSPs, Labels, justification regarding different sizes and ISO-13485/GMP certificate.
42.	M/s KM Enterprises, KM Mansion, 605-D	Legal Manufacturer:	BIOMAX (Latex Examination	Latex Examination Gloves	• Deferred for submission
	Block MA Johor Town Lahore	M/s Biomax Ruber Industries SDN BHD.	Gloves) Class-A		of technical details of mfg., QC,
	ELI: 00054.	Malaysia+			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	AMD SURGICAL Disposable Face Mask (Face Mask) Class-A Shelf Life: N/A	Face Mask	• Deferred for submission of technical details of mfg., QC, EPSP and 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
	M/o Wossess	Local	LATEX	Examination	on. So, you're advised to apply on the relevant form (i.e, Form- 7A) along with differential fee.
44.	M/s Waseem Brothers; Plot No. B-45, Block 5, Gulshan-e-Iqbal, Karachi.	Legal Manufacturer: Top Gloves SDN. BHD, Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E Malaysia.	Examination Powdered Gloves. Class: A	Examination Powdered Gloves	Deferred; 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.

	-do-	Legal	NITRILE	NITRILE	Deferred;
45.	uo uo	Manufacturer:	Examination	Examination	firm asked to
		Top Gloves	Powdered	Powdered	provide ISO
		SDN. BHD, Lot	Gloves.	Gloves	certificate,
		4969, Jalan	GIO V GS.		justifiable
		Teratai Batu 6,	Class: A		stability
		Off Jalan Meru,			study data,
		41050 Klang,			technical
		Selangor D.E			details of
		Malaysia.			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
					-
					l by MDB
	M/s. Hakimsons	Legal	OXYGEN	OXYGEN	by MDB. Approved
46.	M/s. Hakimsons (Pvt) Ltd	Legal manufacturer:	OXYGEN MASK.	OXYGEN MASK	Approved
46.	(Pvt) Ltd.,	manufacturer:	MASK.	OXYGEN MASK	Approved subject to
46.	(Pvt) Ltd., House A-58/B,	•			Approved subject to provision
46.	(Pvt) Ltd.,	manufacturer: Ningbo MFLAB	MASK.		Approved subject to
46.	(Pvt) Ltd., House A-58/B, SITE,	manufacturer: Ningbo MFLAB Medical	MASK.		Approved subject to provision of ISO-13485,
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir	manufacturer: Ningbo MFLAB Medical Instruments Co.	MASK.		Approved subject to provision ofISO-13485, QA
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road,	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N)	MASK.		Approved subject to provision ofISO-13485, QA Certificate
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI-	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou	MASK.		Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI-	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic	MASK.		Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI-	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment	MASK.		Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI-	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145,	MASK.		Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China	MASK. Class: B	MASK	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI-	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal	MASK. Class: B	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved
46.	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer:	MASK. Class: B LARYNGEAL Mask Airways.	MASK	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB	MASK. Class: B	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485,
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co.	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N)	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf
	(Pvt) Ltd., House A-58/B, SITE, Manghopir Road, Karachi. (ELI- 00396)	manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic	MASK. Class: B LARYNGEAL Mask Airways.	Mask	Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin and shelf life Approved subject to provision ofISO-13485, QA Certificate and valid LoA & FSC of country of origin

48.		-do-	Legal	Nebulizer Mask.	Nebulizer	Annroyed
49. Trading and Maintenance Private Limited, 654-D, Canal view, Lahore. 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 CANADA Surgical Disposable Face Mask. Class: A Disposable Face Mask. Class: A Disposable Face Mask. Class: A Original ad valid FSC of country of origin. original agency agreement. valid ISO-13485 certificate. technical information for manufacturing, QC and EPSPs, Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be	48.		manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145,			subject to provision of ISO-13485, QA Certificate and valid LoA & FSC of country of origin and
	49.	Trading and Maintenance Private Limited, 654- D, Canal view,	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:	CANADA Surgical Disposable Face Mask.	Disposable	provision of folowing documents:- • original and valid FSC of country of origin. • original agency agreement. • valid ISO-13485 certificate. • technical information for manufacturi ng, QC and EPSPs, • Brand name includes CANADA while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which

	-do-	Legal	MEDILINK	Surgical Nurse	Deferred for
50.		Manufacturer:	CANADA	Cap.	provision of
			Surgical Nurse		folowing
		M/s. SUMBOW	Cap.		documents:-
		MEDICAL	Class: A		
		INSTRUMENTS			• original and
		CO., LTD.			valid FSC
		,			of country
		Manufacturing			of origin.
		Site: 14F-01, No.			• original
		2 Building			agency
		Shangdong			agreement.
		Business Center,			• valid ISO-
		#1926 Canghai			13485
		Road, Yinzhou,			certificate.
		Ningbo 315041,			• technical
		China			information
					for
		FSC: China			manufacturi
		Date of Issue:			ng, QC and
		07-05-2019			EPSPs,
					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.
	-do-	Legal	MEDILINK	Surgical	Deferred for
51.		Manufacturer:	CANADA	disposable	provision of
			Surgical	Shoe	folowing
		M/s. SUMBOW	disposable Shoe		documents:-
		MEDICAL	Cover.		
		INSTRUMENTS	Class: A		• original and
		CO., LTD.			valid FSC
		M 6			of country
		Manufacturing			of origin.
		Site: 14F-01, No.			• original
		2 Building			agency
		Shangdong Pusings Contar			agreement.
		Business Center,			• valid ISO-
		#1926 Canghai			13485

52.	-do-	Road, Yinzhou, Ningbo 315041, China FSC: China Date of Issue: 07-05-2019 Legal Manufacturer: M/s. SUMBOW	MEDILINK CANADA Surgical Nebulizer Mask.	Surgical Nebulizer Mask	certificate. • technical information for manufacturi ng, QC and EPSPs, • 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. Deferred for provision of folowing documents:-
		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	Class: B		 original and valid FSC of country of origin. original agency agreement. valid ISO-13485 certificate. technical information for manufacturi ng, QC and EPSPs, Brand name includes CANADA while product is from CHINA.

	-do-	Legal	MEDILINK	Surgical	Brand name gives impression of claim of the products from CANADA, which needs to be rectified. Deferred for
53.	-40-	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	CANADA Surgical Oxygen Mask. Class: B	Surgical Oxygen Mask	 peterred for provision of folowing documents:- original and valid FSC of country of origin. original agency agreement. valid ISO-13485 certificate. technical information for manufacturing, QC and EPSPs, 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.
54.	M/s S.Ejazuddin& Co., PO Box 5629, Zia Plaza,	Legal Manufacturer: Ansell Lank	ENCORE Latex ortho- Surgical Gloves. (Powder-free)	Latex ortho- Surgical Gloves. (Powder-free)	Deferred for provision of following documents:

	Altaf Hussain	(Dr.t) I + A	Class B		
		(Pvt) Ltd.,	Class D		
	Road,	Biyagma Export			1 4
	Karachi.	Processing Zone			• complete
	(ELI-00078)	Biyagama-			technical
		Srilanka			info. Of
		/EGG G :1 1			mfg.
		(FSC Srilanka			• QC details,
		22-06-2011)			• valid Full
					QA
					Certificate
					of
					manufactu
					rer.
					 original &
					valid
					agency
					agreement.
					• FSC of
					SRA with
					the instant
					product,
					with all
					coded
					particulars
	M/s Imtiaz	Legal	STERILE	STERILE	Deferred for
55.	Brothers,	Manufacturer	SURGICAL	SURGICAL	provision of
	Suits#7B, 2 nd		Face Mask.	Face Mask	original and
	Floor, Abrar	M/s Guangzhou	Class-A.		valid FSC of
	Business Center,	Fuzelong Hygiene			country of
	25-Main	Material Co., Ltd			origin,
	XX7 - 1 - 1 - 4 D 1				
1	Wahdat Road,	12 # Guancum			original
	Lahore.	Road Jiangpu			agency
	,	Road Jiangpu Street Conghua			agency agreement,an
	Lahore.	Road Jiangpu Street Conghua District			agency agreement,an d
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City			agency agreement,an d justifiablestab
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic			agency agreement,an d justifiablestab ility study
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China			agency agreement,an d justifiablestab ility study data for the
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic			agency agreement,an d justifiablestab ility study data for the claimed
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China			agency agreement,an d justifiablestab ility study data for the
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China			agency agreement,an d justifiablestab ility study data for the claimed
	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China			agency agreement,an d justifiablestab ility study data for the claimed
	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020	DICHOGARIE	Diameter 11	agency agreement,an d justifiablestab ility study data for the claimed shelf-life.
56	Lahore.	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal	DISPOSABLE	Disposable	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020	SURGICAL	Surgical	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer	SURGICAL Gown &	Surgical Gown &	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou	SURGICAL Gown & Isolation Gown.	Surgical Gown & Isolation	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou Fuzelong Hygiene	SURGICAL Gown &	Surgical Gown &	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of country of
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou Fuzelong Hygiene Material Co., Ltd	SURGICAL Gown & Isolation Gown.	Surgical Gown & Isolation	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of country of origin,
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum	SURGICAL Gown & Isolation Gown.	Surgical Gown & Isolation	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of country of origin, original
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu	SURGICAL Gown & Isolation Gown.	Surgical Gown & Isolation	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of country of origin, original agency
56.	<u>Lahore.</u> <u>ELI: 00133.</u>	Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China Valid Till: 07-06- 2020 Legal Manufacturer M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum	SURGICAL Gown & Isolation Gown.	Surgical Gown & Isolation	agency agreement,an d justifiablestab ility study data for the claimed shelf-life. Deferred for provision of original and valid FSC of country of origin, original

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

60.	-do-	Legal Manufacture 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	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-	Legal Manufacture 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	Approved 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-	Legal Manufacture 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)	Approved 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-	Legal Manufacture 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	Approved subject to provision of original and valid FSC of country of origin. (firm provides the FSC issued

	-	Vinghou District		1	h. CCI
		Yinzhou District,			by CCI,
		Ningbo, China			China) and
					valid ISO-
					13485
					certificate and
					shelf life.
	M/s Abbott	Legal	M24sp	(PCR	i. Deferred
64.	Laboratories	Manufacturer:	Instrument.	Analyzer.)	for
	(Pakistan) Ltd.	M/s Abbott	(PCR Analyzer.)	(IVD-	provision
	Opp. Radio	Molecular Inc.	(IVD-Machine)	Machine)	of
	Pakistan	1300 East Touhy			folloeings:
	Transmission	Avenue Des	Class: C		In
	Centre,	Plaines, IL			accordanc
	Hyderabad	60018, USA			e with
	Road, Landhi,	,			5(vi) of
	Karachi	Manufacturing			form-7A
	(ELI-00019)	Site			provide
		M/s Tecan			the ISO-
		Schweiz AG 103			13485/
		Seestrasse			GMP
		Maennedorf			certificate;
		Zuerich, Zurich,			ii. Provide
		8708			service life
		Switzerland.			protocols
		Switzeriand.			& studies.
		FSC USFDA			Grouping and
		Valid Till			components
		(30-01-2021)			of the subject
		(30-01-2021)			product (that
					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
					product
					should be
					classified in
					higher risk
					class, i.e.,
					class-C and
1					you're

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

	-do-	Legal	Oxygen Mask	Oxygen Mask	The Board
67.		manufacturer:	and Accessories	• •	considering
		M/s. HSINER			the Policy
		Co., Ltd 312	Oxygen Mask		Guidelines
		Jhongshan Rd,	and Accessories		on Taiwan
		Shengang Dist,			sent by
		Taichung 429	35171-35173,		Ministry of
		Taiwan	35175,35178,35		Foreign
		FSC: 180aiwan	113		Affairs
		Date of issue:	Class: B		
		14.11.2019.	Shelf life 3		rejected the
			years.		request of
					M/s
					Cardiac
					Care,
					Lahore for
					registration
					of their
					product
					namely
					Oxygen
					Mask and
					Accessories

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	Approved.
2.	-do-	Lifemed Citric Acid 30% (3NLCA30)	Decalcificator/disinfectant for Haemodialysis Machine	Approved.

		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	Approved.
4.	-do-	Lifemed Citric Acid 50% (3NLCA50) Shelf Life: 3 Years Class C Rs. 20,000/-	Decalcificator/disfectant for Haemodialysis Machine	Approved.

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

Sr.	Name & Address of	Name of Medical	Brief	Decision of MDB
No.	Establishment	Devices With Size	Description	
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.	Deferred for product specific inspection.

2.	Karim Industries, 135- C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014)	Sizes. 12mm x4.5m 25mm x 4.5m 50 mm x 4.5m 75 mm x 4.5m 100 mm x 4.5m Soft Med Mask (Surgical Mask KN-95) Class A Shelf Life: 03 Years Rs.5000/-	Surgical Mask KN-95	Deferred 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	Deferred 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 BP0.5% 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.	Deferred for inspection to verify the testing facility for Chlorhexidine acetate.

Class: C Shelf Life: 03 Years	
Rs. 10,000/-	

23. <u>REGISTRATION OF RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)</u>

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.	Approved.

24. <u>DEFERRED CASE OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.</u>

Following application for registration of Medical Devices for manufacturewas placed before the MDB in its 24^{th} meetings and deferred for provision of document. Now the firm has submitted the documents

S.#	Name of Firm (s)/manufactur e	Name of Medical Device	Brief Desciption	Decision of MDB
1.	M/s Renacon Pharma ltd. Lahore.	Renapulv-N Hemodialysis concentrate	Used In Hemodialysi s Of Kidney Failure	Approved.
		Hemodialysis Concentrate Shelf Life: 2 years	Patients	

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.	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Auto Disable Syringe. Class B Sizes as per FSC 0.5ml, 1ml, 2ml, 5ml	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
02	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA 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	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
03.	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA 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) 1.1x48mm (20Gx1.16IN) 1.1x48mm (20Gx1.88IN) 1.3x30mm (18Gx1.16IN) 1.3x48mm (18Gx1.88IN) 1.6x55mm	Approved 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-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Blood Transfusion Set Class B Codes & Sizes as per FSC.	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
05.	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Infusion Set Class B Codes & Sizes as per FSC.	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
06.	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Disposable Insulin Syringe Class B Codes & Sizes as per FSC.	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
07.	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Disposable Syringes (3ml, 5ml, 10ml and 20ml) Class B Codes & Sizes as per FSC.	Approved subject to provision of valid QMS Certificate, EPSPs and FSC of reference country as per Rule 67& 71, of MDR, 2017.
08.	-do-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd.	ALPHA Brutte Chamber 100 ml	Approved 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-	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry, Nanchang City, Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Disposable Syringes (50ml) Class B Codes & Sizes as per FSC.	Approved 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	Name of	Name of	Decision of MDB
	(s)/Importer	Manufacturer	Medical Device	
1.	M/s Grace Pharmaceuticals office # 103,5 th 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.	Approved subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, original 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.	Approved subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, original 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.	Approved subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, original 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	Approved subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, original and

	Country, Jiangxi Province, China FSC: China	as per FSC.	valid agency agreement & FSC of country of origin as per MDR, 2017.
-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.	Approved subject to provision of technical details of mfg.& QC, justifiable stability study data for claimed shelf life, original and valid agency agreement & FSC of country of origin as per MDR, 2017.
