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

MINUTES OF THE 15TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 30-12-2019

15th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 30thDecember, 2019. The Secretary MDB referred to Sub-rule (9), Rule (59) of Medical Devices Rules, 2017 where in the absence of Chairman MDB, members may elect one of the member to preside over the meeting. The members unanimously elected Dr. Prof. Saqib Shafi Sheikh, Executive Director, Punjab Institute of Cardiology, Lahore to preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Prof. Saqib Shafi Sheikh, Executive Director, Punjab Institute of Cardiology, Lahore and was attended by the following:-

S.No.	Name and Designation / Department	Position in the MDB
1.	Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore.	Chairman
2.	Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
3.	Mr. Imdad Ullah Baloch, Secretary, PQCB, Health Department, Balochistan, Quetta. (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
4.	Brig (R) Dr. Waqar Asim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hopspital, Golra More, Islamabad.	Member
5.	Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar.	Member
6.	Mr. Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore.	Member
7.	Dr. Prof. Saqib Shafi Sheikh, Executive Director, Punjab Institute of Cardiology, Lahore.	Member

8.	Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha, Sargodha.	Member
9.	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.	Secretary / Member

The meeting commenced with the recitation of the Holy Quran. The Secretary MDB welcomed all the participants and presented the agenda of the meeting.

Item No.I. **CONFIRMATION OF MINUTES OF 14TH MEDICAL DEVICE BOARD MEETING.**

Decision: The Board confirmed the minutes of the 14th meeting of MDB.

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

The following firms have applied for grant of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The inspections were conducted according to the Checklist. Recommendations were placed before the MDB for consideration.

Decision:-The MDB decided as mentioned against each:-

S.No	Name of Establishment	Director/Proprietor / partners	Name of panel Inspector (s)	Cold Chain (Yes/No)	Decision
1.	M/s Care Scientific, 13-14, C/A Ist Floor Chuburji Center Multan Road Lahore.	Mr. Amir Khan	Ajmal Sohail Asif, FID, DRAP, Lahore. Dr. Akbar Ali, Assistatn Director, DRAP, Lahore.	No	**Approved** for storage of non-cold chain medical devices.
2.	M/s Safe Line, 52-D, PGHS, Mohlanwal, Multan Road,Lahore.	Ahmad Faraz Langah.	-do-	No	**Approved** for storage of warm range medical devices without cold chain facility
3.	M/s Advance System, 630 Shadman Colony-1, Lahore.	1.Sabir Ali Hussain 2.Mahboob Haider 3.Ammar Alam. 4.Waseem Mazhar Mirza 5.Anbreen Zafar.	-do-	No	**Rejected,** as the storage conditions at the premises were not satisfactory; the ceiling of store

	Godown - Same as above.				room was made of naked bricks and T.R without plaster, the walls were rough and paint flakes were shredding. Open exhaust vents and drains were present. Firm has a small wooden made bird house near sotragte room which was shredding fibers in air, the floor was dusty at the time of visit. Firm has provided a room declared as reparing room, which was without proper repairing / maintained facilities. Recall room was not available. SOPs were present but proper recall system was not established.
4.	M/s Decent Traders, 1st floor, KH 2312, Tape Road, Sheesh Mehal, Near UVAS, Lahore. **Godown:Same As above**	Mr. Mohammad WaseemTipu	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
5.	M/s Opti Med, 2nd Floor Hassan Plaza 6-A Jail Road, Lahore. **Godown:Same As above**	Mr. Shafique Ur Rehman	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
6.	M/s Scientific House, 13-C First Floor Chaburgi Center Multan Road,	Mian Muhammad Muzammal	-do-	Yes	**Approved** for room temperature medical devices alongwith cold chain facility.

	Lahore. **Godown Address**: Upper Floor, 51-Chauburji Center, Chauburji, Lahore.				
7.	M/s Medical Equipment & Systems, 60/61, F.C.C. Syed Maratib Ali Road, Gulberg-4, Lahore	Mst. Erum Omer. Mr. Zeb Kabir Ahmad. Mst. Ayesha Zahid Sethi.	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
8.	M/s FDS (Pvt) Ltd., Flat No.8, 1st Floor, Ganga Ram Mansion Shahrah-e-Quaid-e-Azam, Lahore	Mr. Changez Yusuf Mumtaz Ms. Qudsia Mumtaz	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility
9.	M/s Don Valley Pharmaceuticals (Pvg) Ltd, 15-C/2, Vogue Tower, Gulberg III, MM Alam Road, Lahore. **Godown**: Same as Above	1.Dr. Shahla Javed 2.Mr. Saad Javed Akram 3.Mr. Abdul Shabbir Khokhar	Mr. Shoaib Ahmed, FID, DRAP, Lahore. Mrs. Anam Saeed, AD, DRAP, Lahore.	No	**Approved** for storage of non-cold chain medical devices only.
10.	M/s Tianshi International Pakistan Co.,(Pvt) Ltd, Head Office: 1st Floor, Banner Store Plaza, Block 20-A, Main Civic Center, G-8 Markaz Islamabad. **Godown:** Basement, Banner Store Plaza, Block 20-A, Main Civic Center, G-8	Mr.Li Jinyuan Mr. Yan Yupeng Mr. Li Tao	Mrs. Unum Zia Shamsi, Assistant Director-IV (MD&MC), DRAP, Islamabad. Mr. Adil Saeed, Assistant Director (QA&LT), DRAP, Islamabad.	No	**Approved** for storage of room temperature medical devices without cold chain facility.

	Markaz Islamabad.				
11.	M/s Apex Services, Office No. 1 & 2 First floor, Building No. 69, Al-Malik Plaza, Chour Chowk Main Peshawar Road Rawalpindi. **Godown**: Same as Above	Muhammad Usman Shah	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility.
12.	M/s Health Care Solutions, Shop No.51-52, 2nd Floor, Ghakkar Hathyal, Main Simly Dam Road, Barakahu, Islamabad. **Godown**: Same as Above	Tauseef Qureshi	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility.
13.	M/s Arham Enterprises, Plot No. 95, Mezzanine Floor, Kashmir Arcade, Blue Area, Islamabad. **Godown**: Same as Above	Mr. Ahsan Zafar Bakhtawari	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
14.	M/s Sapphire Consults, Office No.209, 2nd Floor, Royal Center, 106-West, AK Fazal-e-Haq Road, Blue Area, Islamabad. **Godown**: Same as Above	Mr. Farhan Khan Mr. Hammad Khan	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility.
15.	M/s Lab Diagnostic	Mr. Zafar Mehmood	-do-	No	**Approved** for storage of room

	Systems (SMC) Pvt. Ltd, 111-B, Hali Road, Westridge-1, Rawalpindi. **Godown**: Plot No.36, Industrial Estate, Wah Cantt.				temperature medical devices without cold chain facility subject to provision of copy of DSL.
16.	M/s Oasis Medical System, House No. A-86, Block C, Ground Floor, Gulshan-e-Jamal, Karachi. **Godown**: Same as Above	Mrs Zaib-un-Nisa Mrs Ashie Amber	Mr. Awais Ahmed, Federal Inspector of Drugs, DRAP, Karachi. Mrs. Unum Zia Shamsi, Assistant Director-IV (MD&MC), DRAP, Islamabad.	No	**Approved** for storage of room temperature medical devices without cold chain facility subject to provision of copy of DSL.
17.	M/s R.G. Pharmaceutica (Pvt). Ltd, Head Office. No. 703, Progressive Square, Block-6, P.E.C.H. S, Shahrah-e-Faisal, Karachi. **Godown**: Plot No. 35-B, Block-6, P.E.C.H.S, Shahrah-e-Faisal Karachi.	Mr. Muhammad Naveed Butt (CEO) Mr. Sajjad Haider Ms Rubina Khalid Mr. Mian Khalid Mehmood	-do-	Yes	**Approved** for storage of room temperature medical devices alongwith cold chain (2-8°c) facility.
18.	M/s Aswad Medical Co. C-2, 3rd Floor, Rahat Jo Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi. **Godown: D-5, 4th Floor,** Rahat Jo Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi.	Muneeza Saleem.	-do-	No	**Approved** for storage of warn range temperature medical devices without cold chain facility.
19.	M/s Sawanki & Co, C-211,	Mr. Kafeel Ahmed	-do-	No	**Approved** for storage of room

	Sector 35-A Korangi, Township, Karachi. **Godown**: Same as Above	Muhammad Irfan Khan			temperature medical devices without cold chain facility.
20.	M/s International Sales & Services, 302, Noor Estate, Shahrah-e-Faisal, Karachi. **Godown**: Same as Above	Syed Farrukh Hamid	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility.
21.	M/s Cedar Pharma, A-85, 1st Floor,S.M.C.H.S , Karachi, **Godown**: Same as Above	Mr. Amin Ul Haq Mr. Wajiha Atif Mst. Fatima Haseeb	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility. .
22.	M/s TransHeal Pharma (Pvt) Limited, 301-A, Jofa Tower, Plot No. SB-23-24, Main University Road, Gulshan-e-Iqbal, Karachi. **Godown**: Same as Above	Muhammad Shariq Mrs. Seema Imran Mr. Muhammad Imran Yousaf.	-do-	No	**Approved** for limited storage facility of room temperature medical devices without cold chain facility.
23.	M/s Molecular Biology Products, 7B-1, 7th Floor, Fakhri Trade Center, Shahra e Liaquat, Karachi. **Godown**: Same as Above	Mr. Mufaddal Feroze Cutlerywala.	-do-	Yes	**Approved** for limited storage facility of room temperature medical devices alongwith cold chain (-20°c) facility.
24.	M/s S.K. Enterprises,	Mr. Vinod Kumar	-do-	No	**Approved** for storage of room

	Office No. 701 7th Floor, KS Trade Tower, Shahra-e-Liaquat, Karachi. **Godown**: Same as Above				temperature medical devices without cold chain facility.
25.	M/s Arfi International, Office No. 904, 9th Floor, Al Rahim Tower, I. I. Chandrigar Road, Karachi. **Godown**: Same as Above	Mr. Altaf Gauhar Paracha	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
26.	M/s Penicon, Ground Floor, C-91, Block 10 Federal B Area, Karachi. **Godown**: Same as Above	Mr. Asghar Ishaq Mr. Muhammad Zahid Asghar	-do-	Yes	**Approved** for storage of room temperature medical devices alongwith cold chain facility.
27.	M/s Physionics, Suit# 7, 40-C, Main Khayaban-e- Bukhari, Bukhari Commercial Area, Phase 6, D.H.A, Karachi. **Godown**: Same as Above	Mr. Fakhar Islam	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
28.	M/s Mezrab, Head Office. No 25-C, Commercial Area, Old Sunset Boulevard, DHA Phase-II, Karachi. **Godown**: Basement Plot No.C-21, Sector	Dr. Sarah Saleem Mr. Afshaan Haroon Jafri. Jameel Yousaf.	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

	6-F, Mehran Town, Korangi Industrial Area, Karachi.				
29.	M/s Health Services, Apartment No. A-3, (3rd Floor) Plaza No. 08, Civic Centre, Phase IV, Bahria Town, Islamabad. **Godown**: Same as Above	Mr. Haroon-ur-Rasheed	Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad. Mr. Ishtiaq Shafiq, Assistant Director (QA&LT), DRAP, Islamabad.	No	**Approved**for storage of room temperature medical devices without cold chain facility.
30.	M/s Sultan Health Care, Saadat Plaza, Main Shahpur Road, Adyala Road, Rawalpindi. **Godown**: Same as Above	Mr. Nasir Ali	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
31.	M/s Solutions For Efficient Engineered Design Pvt, Ltd, Building No 1, Civic Center, Phase-IV, Bahria Town, Islamabad. **Godown**: Same as Above	Mr. Shahid Asif Mr. Zammar Shahid.	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
32.	M/s Global Health Care, Office No.41-A, Street No.15, Near Foundation School, Race Course Ground, Westridge, Rawalpindi.	Mr. Asif Mahmood	-do-	Yes	**Approved** for storage of room temperature medical devices alongwith cold chain facility.

	Change of Office and Godown Address as mentioned below: M/s Global Health Care, Midway Commercial Plaza No.20, Back Side Prism Arcade No.2, Bahria Phase-7, Rawalpindi. **Godown**: Same as Above				
33.	M/s RA Healthcare (SMC-Pvt) Ltd, 2nd Floor, Building No. 50, Mir Arcade, Mini Commercial, Phase 7, Bahria Town, Islamabad. **Godown**: Same as Above	Mrs.Zareen Nadeem	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
34.	M/s Seignior Pharma, Farzana Building, Suit No. 12, 3rd Floor, Plot No. E-2, Block No. 7 & 8, K.C.H. Union Commercial Area, Shaheed-e-Millat Road Karachi.	Yasinullah Khan	Dr Mr. Sajjad Abbasi, FID, Quetta (Based at Karachi) DRAP, Karachi. Hafiz Muhammad Asif Iqbal, Assistant Director-V (MDMC), DRAP, Islamabad	No	**Rejected** due to the reason that no technical staff was present at the time of inspection. A room which was like dinning hall but no separate storage facility was present for the storage of medical devices. Even minimum requirements as per GDPMD checklist were not met.
35.	M/s N.S Corporation, Shop No. 3, Plot No. 22-C, Rahat Lane No. 1,	Naheed Saleem	-do-	No	**Approved** for storage of room temperature medical devices without cold chain

	Phase-VI, D.H.A, Karachi **Godown**: Same as Above				facility.
36.	M/s Surgi Pharm, B-1&2, Basement Floor, Plot No. 34-C, Rahat Commercial Lane No-2, Phase VI, DHA, Karachi. **Godown**: Same as Above	Mohsin Ghani Sodagar	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
37.	M/s Bone Solution, Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A. Karachi. **Godown**: Same as Above	Mr. Zain Iqbal Mr. Zafar Iqbal	-do-	No	**Approved** for storage of warn range temperature medical devices without cold chain facility.
38.	M/s Surgilink, Shop No. 234, 2nd Floor, International Centre, Saddar, Karachi.	Muhammad Saeed	-do-		**Rejected** due to lack of proper and inadequate storage facility with respect to the bulk/huge quantity of disposable syringes with the firm intends to import.
39.	M/s Concept Medical Centre Private Limited, 32-A, Rojhan Street, Block-5, Kehkashan, Clifton, Karachi.	Syed Ahmer Sajjad Syed Aamir Sajjad Syed Omair Sajjad Syed Sumair Sajjad	-do-		**Rejected.**The medical center has limited /inadequate storage facility for the storage of medical devices. Center also uses the same facility for the storage of medicines. They want to import medical devices for their own centers

					but there is no surety that they will not sell their products on commercial scale. The center is also not a charitable institute.
40.	M/s Optical Palace, Hemani Mension, M.A. Jinnah Road, Opp. K.M.C, G.P.O. Box No.1249, Karachi. **Godown**: Same as Above	Atif Jamil Ur Rehman Aamir Rehman Akif Rehman	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
41.	M/s Interactive Solutions (Pvt) Ltd., Ibrahim Trade Tower, Main Shahrah-e-Faisal, Karachi.	Mr. Ali Habib Mr. Aamir Javed Mst.Lubna Javed	-do-		**Rejected.**The firm wants to import an ampule which is used in the callibration of a medical device (machine for TB diagnostic) and said that they do not need DSL as they do not sale anything but only provide services. The Board was of the opinion that the firm /company which wants to calibrate equipments should import the calibration ampoules.
42.	M/s Nassir Trading Company, Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp,	Mr. Nasir Mehmood	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

	Sindh Madrasa, Karachi. **Godown: Office No.214, 2nd Floor,** Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp, Sindh Madrasa, Karachi.				
43.	M/s Global Technical Services, Suite No. 1 & 2, 3rd Floor, Nadir House, I.I.Chandrigar Road, Karachi. **Godown**: Same as Above	Asif Ali Siddiqui	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
44.	M/s Respro Care, Plot No. 18-C, Naseem Arcade, Stadium Commercial Lane IV, Street 14th, Phase V, D.H.A., Karachi. **Godown**: Same as Above	Muhammad Asif Oswala	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
45.	M/s Hikmat Trading Company, E/8, Naveed Bungalows, Block 17, Gulistan-e-Jauher, Karachi. **Godown**: Same as Above	Mr. Yasir Ullah Khan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
46.	M/s Qualitron Corporation, E-172, Block 2, Tariq Road,	Muhammad Tazam Shaikh	-do-	No	**Approved** for storage of room temperature medical devices

	P.E.C.H.S., Karachi. **Godown**: Same as Above				without cold chain facility.
47.	M/s Siddiqui& Company, Plot No.3-C-9/3B, Shumail Terrace, Nazimabad No.3, Karachi. **Godown**: Same as Above	Mr. Amir Anis Mr.Khurram Anis	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
48.	M/s UM Enterprises, Plot No.12, Sector 15, Korangi Industrial Area, Karachi. **Godown**: Same as Above	Muhammad Umer Muhammad Iqbal Badaruddin Liaquat Ali Malik Muhammad Ali Malik	-do-	Yes	**Approved** for storage of warm range medical devices alongwith cold chain facility.
49.	M/s RB Innovate (Pvt) Ltd, Office No H 13 First Floor Muhammadi Plaza, Blue Area Islamabad.	Adil Raza Bhatti	Muhammad Ayub Naveed, AD-II (MDMC), DRAP, Islamabad Hafiz Muhammad Asif Iqbal, Assistant Director-V (MDMC), DRAP, Islamabad.		**Rejected** as the firm has no storage facility and office also shared with other firm. Qualified person is also not present. Only a staff member was present.
50.	M/s Clinical Life Inc, House: 530-B (Third Floor) B-Block Satellite Town, District Rawalpindi.	Mr. Bilal Ahmed	Mrs. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. Mr. Arsalan Tariq, Assistant Director (QA&LT), DRAP, Islamabad.	No	**Rejected** due to lack of storge facility and documents as per GDPMD checklist.
51.	M/s The Healers, 206-2, D-Block Satellite Town Rawalpindi.	Mr. Chaudhary Irshad Ahmed.	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

	Godown: Same as Above				
52.	M/s Multi Pharma, D-206/2 Satellite Town, Rawalpindi.	Mr. Khalid Javed Kiani	-do-	No	**Rejected** as the firm has withdrawn their application for grant of establishment licence to import medical devices stating that their product is a drug and not a medical device.
53.	M/s Allied Business System, Office No B-305, 1ST Floor, Chandi Chowk, Rawalpindi	Mr. Babar Shahzad.	-do-	No	**Rejected** due to inadequate storage facility for storage of medical devices and lack of documents as per GDPMD checklist.
54.	M/s Medident Supplies & Services, NW.695/3, Near Kali Tanki Stop, Main Said Pur Road, Rawalpindi. **Godown**: Same as Above	Mr. Nabi Amin Mr.Zia-ur-Rehman	-do-	No	**Approved** for storage of room temperture medical devices without cold chain facility.
55.	M/s Med-n Tec Pharma, D-574, Shafi Street, Satellite Town Rawalpindi. **Godown**: Same as Above	Ehtesham Rauf Malik Amjad Tahir Irfan Qureshi	-do-	No	**Approved** for storage of room temperture medical devices without cold chain facility.
56.	M/s Hyderabad Dental Supply Co, Flat No 104/B-36 Block 13-A, Gulshan-e-Iqbal, Karachi.	Muhammad Arif Khan	Mr. Sajjad Abbasi, FID, Quetta (Based at Karachi), DRAP, Karachi. Mrs. Hira Bhutto, Assistant Director-I (MD&MC), DRAP,	No	**Approved** for storage of room temperture medical devices without cold chain facility.

			Islamabad.		
57.	M/s Dynamark International, 410-B, Anum Classic B, Near Baloch Colony Bridge, Shahrah-e-Faisal, Karachi.	Mr. Jawed Lodhi	-do-	No	**Approved**for storage of room temperature medical devices without cold chain facility
58.	M/s A.H. Sons, E-10 Naveed Bungalows, 17 Gulistan –E-Jauhar, Karachi.	Mr. Ashfaq Ahmed Ashraf Ahmed Azmi Jehanzaib Ashfaq Azmi Omar Ashfaq Azmi Asad Ashfaq Azmi	-do-	No	**Approved** for storage of warm range temperature medical devices without cold chain facility**.**
59.	M/s Silpha Labs (Pvt.) Ltd, 99/6, Gulshan-e-Mehrunnisa, Ibrahim Hyderi, Korangi Creek, Karachi.	Mr. TaimurUsman Mr. FaizanUsman	-do-	No	**The MDB acceded to the request of the firm for postponment of inspection and grant some time for preparation as per GDPMD Checklist.**
60.	M/s East Health Care, A-17/1, Block 6, Gulshan-e-Iqbal, Karachi.	Mr. Salahuddin	-do-	No.	**Rejected**due to lack of dedicated storage facility for medical devices and documents as per GDPMD checklist.
61.	M/s Kokab Enterprises, Shop# G-56, Billy's Shopper's Galleria Gulistan-e-Jauhar Block 18, Karachi. **Godown Address:** A-406, Billy's Shopper's Galleria and	Ms. Rukhshanda Azam	-do-	No	**Approved** for storage of warm range medical devices without cold chain facility.

	Residency, Gulistan-e-Jauhar Block 18, Karachi.				
62.	M/s Dolphin Care, Plot No. FLS-IV/1-36, Sector IV, Ahsanabad Town, Maymar Ahsan Bungalows Gulshan-e-Maymar, KDA Scheme No.33, Karachi	Muhammad Asad Ghouri Mr. Hamza Zulfiqar Muhammad Akbar Khan	-do-	No	**Approved** for storage of room temperature medical deviceswithout cold chain facility subject to submission of SOPs as per GDPMD checklist.
63.	M/s Kain Medical, Ali, Office No. 35, 3rd Floor, Plot No.233-A, Bhai Center, PECHS Block No. 2, Karachi	Mr.Kashif Saleem	-do-	No	**Approved** for limited storge facility for room temperature medical devices without cold chain facility.
64.	M/s Medicos Marketing, 126 First Floor, Al-Amnna Plaza, opposite Capri Cinema, M.A Jinnah Road, Karachi.	Mr. Kaleem Mirza	-do-		**Approved** for storage of room temperature medical devices without cold chain facility subject to addition of godown address in DSL.
65.	M/s DKT Pakistan (Pvt.) Limited, RJ, Building, 4th Floor, Plot No. 37-C, Stadium Lane, Comm. Area, Phase V, DHA, Karachi. **Godown Address:** TCS Logistics (Pvt) Limited, Plot No.V-1, Survey No.258, Sector No.2,	Syed Sadaqat Ali Jafri, Muhammad Dawar Waraich Christopher Houston	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

	Korangi Industrial Area, Karachi.				
66.	M/s Alam Enterprises, B-22, Sector W-1, Gulshan-e-Maymar, Karachi.	Mr. Shahnawaz Alam	-do-	No	**Approved** for storage of room temperture medical devices without cold chain facility.
67.	M/s Keyyani Medical Solutions, 424-Mashrique Centre, Sir Shah Suleman road, Gulshan-e-Iqbal, Block 14, Karachi.	Mr. Saghir Ahmed Mrs. Fozia Saghir	-do-	No	**Approved** for storage of room temperature medical devices and limited facility fror temperature sensitive medical devices.
68.	M/s Agfa Pakistan (Pvt) Ltd., Carim's House, RB-5/8, Arambagh Road, Pakistan Chowk, Karachi. **Godown Address:** 28/29,Timberpo n, Kiamari, Karachi.	Mr. Abdul Majid Carim. Mr. Sohail Majid Carim.	-do-	No	**Approved**for storage of room temperature medical devices without cold chain facility **subject to provision of DSL**.
69.	M/s Fujifilm Pakistan, 37-D, Block-6, P.E.C.H.S., Karachi.	Syed Jameel Hussain	-do-		**The MDB acceded to the request of the firm for grant of 15 days time to apply for DSL and to prepare themself as per GDPMD Checklist.**
70.	M/s Nishat Surgical., Office No. A-114-296, Jail Road, Hyderabad	Mr. Noor Ahmed	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
71.	M/s G Market, Suit 24 Bilal	Mr. Mian Ahmad Zeb	Muhammad Akhtar Abbas Khan,		**MDB agreed for re- inspection of**

	Business Centre, Ring Road Chowk, Peshawar.		Deputy Director, DRAP, Islamabad. Mr. Shahid Muhammad Iqbal, Assistant Director-III (MD&MC), DRAP, Islamabad.		**the firm.**
72.	M/s AL-Haram Traders, D-18/19 4th Floor Karachi Market Khyber Bazar, Peshawar. **Godown:** Same as above.	Syed Rizwan Ali Shah	-do-	Yes	**Approved** for storage of room temperature medical devices alongwith cold chain facility.
73.	M/s Trans Continental Pharma (Pvt) Ltd, 13-14-B, Gul Plaza, Charsada Road, KPK, Peshawar. **Godown:** Same as above.	Mr. Asmat Asar Mr. Shakir Khan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
74.	M/s Mian Enterprises, UG-400, Deans Trade Center Peshawar Cantt. **Godown**: Same as above.	Mr. Naeem Ullah	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
75.	M/s Medimage Services, Suite No. 5/B Peshawar Medical Centre, Shoba Bazar, Peshawar.	Mr. Amjad Ali	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility subject to provision of godown addess on DSL.
76.	M/s Mediline Technology, Suite No. 29-B, 2nd Floor Karachi Market, Khyber	Mr. Khalid Khan Mr. Ashfaq Ahmad	-do-	No	**Approved** for storage of room temperature medical devices without cold chain

	Bazaar, Peshawar.				facility subject to provision of godown addess on DSL.
77.	M/s A One Traders, Makkah Tower, 3rd Floor Room No. 303, Namak Mandi Peshawar. **Godown**: Same as above.	Mr. Jan Alam	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
78.	M/s Shahid Surgical, Basement Abdul Market, Shop No. 14, Namak Mandi Peshawar. **Godown**: Same as above.	Muhammad Shahid	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility..
79.	M/s Cure Traders (Smc) Pvt Ltd, House No 236, Street No,01 Sector F-08, Phase No 08, Hayatabad, Peshawar. **Godown**: Same as above.	Mr. Muhammad Rafiq	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
80.	M/s Arif & Company, Office No. 3, 1st Floor, Al-Jalil Market, Namak Mandi, Peshawar. **Godown**: Same as above.	Mr. Arif Khan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility..
81.	M/s Al Qazi Marketing Group, 10-11-E, Karachi Market, Khyber Bazar, Peshawar.	Mr. Ihsan-ul-Haq Mr.Inam-ul-Haq	-do-	Yes	**Approved** for storage of room temperature medical devices along with cold chain facility.

	Godown: Same as above.				
82.	M/s Ultimate Step Group, Office# 5,6, Al Noor Plaza Mandi Mour, G.T Road, Haripur.	Mr. Assad Ullah Khan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
83.	M/s Haroon and Sons Surgical, Shop No. 5, Samand Plaza, University Road, Kohat.	Mr. AwaisHaroon	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
84.	M/s IBS Pharmaceuticals, Haji Ghulam Said Market, Shop No.24, Namak Mandi, Peshawar.	Mr. Inamullah Mr. Irfanullah	-do-		**MDB agreed for re- inspection of the firm.**
85.	M/s Jawad Traders, PS Tower, Mall Cdown Road, Near Government Commerce College, Peshawar. **Godown:** Same as above.	Mr. Muhammed Ishaq	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility subject to provision of documents of qualified person.
86.	M/s Electro Med Solutions, 7-D, 4th Floor, Karachi Market, Khyber Bazar, Peshawar. **Godown:** Same as above.	Mr. Rashid Minhas	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility subject to provision of DSL.
87.	M/s Raheem Sons, Shop No	Khalid Mehmood.	Mr. Shahid Muhammad Iqbal,	No	**Approved**for storage of room

	09-10 Nawab Plaza Shalley Velly Range Road Rawalpindi. **Godown:** Same as above.		Assistant Director-III (MD&MC), DRAP, Islamabad. Mr. Hassan Afzaal, Federal Inspector of Drugs, DRAP, Islamabad.		temperature medical devices without cold chain facility.
88.	M/s Medifar Impex, Suit# 403-4, 4th Floor Mohamdia Plaza College Raod, Rawalpindi.	Mr. Tanveer Iqbal Farooqi Mrs. NailaTanveer	-do-	No	**Approved**for storage of room temperature medical devices without cold chain facility.
89.	M/s AA Enterprises, Shop No. 57, 15-16 First Floor Mobi Plaza Saddar, Rawalpindi **Godown:** Same as above.	Mr. Muhammad Waqas Mr. Sajjad Bhatti	-do-	No	**Approvedfor** storage of room temperature medical devices without cold chain facility.
90.	M/s Care Concepts, 19, 3rd Floor, Majeed Plaza, Bank Road, Rawalpindi. **Godown:** CB-98, Mumtaz Colony, Adiyala Road, District Rawalpindi.	Mr.Sohail Akhtar. Mr. Asim Riaz.	-do-	No	**Approved**for storage of room temperature medical devices without cold chain facility.
91.	M/s S.J Traders, Office No. 14, 3rd Floor Majeed Plaza Bank Road Saddar, Rawalpindi. **Godown:** Same as above.	Muhammad Saeed.	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
92.	M/s Capital Dental Supply, Office No. 17, First Floor, Poonch House Complex, Adam Jee Road, Saddar	Mr. Ameer Abdullah	-do-	No	**Approved**for storage of room temperature medical devices without cold chain facility.

	Rawalpindi. **Godown:** Same as above.				
93.	M/s JD Professional Healthcare Services (SMC-PVT) Ltd, 3rd Floor, 310/311, Rania Mall, Bank Road, Saddar, Rawalpindi.	Muhammad Junaid Pirzada (Director)	-do-	Yes	**Approved**for storage of room temperature medical devices with cold chain facility subject to provision of medical refrigerator/ freezer and DSL.
94.	M/s Medtech System, Suit No. 1, 3rd Floor, Abrar Business Center, 25-Main Wahdat Road, Lahore.	Mr. Saqib Amin	Mr. Shoaib Ahmed, FID, DRAP, Lahore. Mst. Uzma Barkat, AD,DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
95.	M/s Zafaryab Traders, 134, First Floor, Eden Center, Jail Road, Lahore.	Mr. Jahangir Khan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
96.	M/s Madina Pharma links, 84-S, Habibullah Road, Garhi Shahu Lahore.	Mr. Muhammad Asim Munir	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
97.	M/s Nipro Medical (Pvt) Ltd, Building No.24, Central Commercial Area, DHA Phase 8, Ex-Park View, Lahore.	Mr. Salman Majeed	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
98.	M/s Medimen, H.No.199 P 2, St.3, G.E.C.H.S. Link Road, Model Town, Lahore.	Mr. Mansoor ul Haq Mst. Munazza Mansoor	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

99.	M/s Varitron, First Floor 60-D, F.C.C. Zahoor Elahi Road, Gulber-IV, Lahore.	Mr. Sohail Ahmed Kabir	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
100.	M/s Medi Bridge, Office No. 5, 2nd Floor, Roayal Arcade, Qainchi Ferozepur Road, Lahore.	Mr. Iftikhar Ahmed	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
101.	M/s Artech Biomed (Pvt) Ltd. 12-A/4, 3rd Floor, Agro Flat, Shadman Market, Shadman 1, Lahore.	Mr. Mumtaz Masood Mrs. Resham Mumtaz	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
102.	M/s MedCom International, House No.230/ 231-A, Johar Town, Lahore.	Mr. Abdul Rauf Anjum	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

Item No. III. **SITE VERIFICATION OF FIRMS FOR MANUFACTURING MEDICAL DEVICES.**

Case No.1. M/s Kamtex Industries, 44-KM, GT Road, Kamoke, Diswtrict Gujranwala has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located amain GT Road, Kamoke, Gujranwala. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Ajmal Sohail Asif, FID, DRAP, Lahore was nominated for inspection of site verification. Inspection report is reproduced as under:-

Location	The proposed site was located at 44-KM, GT Road, Kamoke, Diswtrict Gujranwala. It was located on main GT road having different industries around. The plot was not located

	in commercial or residential area. Location map of the proposed site is attached, taken from the google maps at the time of visit, showing geographical coordinates (31.9430260, 74.2298510) for future reference.
Surrounding	• On the east side of the plot was a rice mill. • On the west side of the plot was a vacant plot and main GT Road. • On the south side of the plot was a vacant plot. • On the north side of the plot was access road and across it was another medical device firm namely Hafiz Pharma.
Size	The size of the plot is 2145 yds approx. as per documents provided.
Recommendations	In the light of physical verification of site and scrutiny of documents provided by the applicant, **the proposed site is suitable for establishment of medical device manufacturing unit.**

Decision: The Board approved the site of M/s Kamtex Industries, 44-KM, GT Road, Kamoke, Diswtrict Gujranwala for establishment of manufacturing unit of medical devices.

Case No.2. M/s Kamoke Pharma Industries, Khewat No.320, Khatooni 416-419, Khasra No.23, Kot Mian Abdul Aziz, Post Office, Alla Abad, Tehsil Kamoke, District Gujranwala has informed that they are interested to install Manufacturing Unit for Medical Devices. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Ajmal Sohail Asif, FID, DRAP, Lahore was nominated for inspection of site verification. Inspection report is reproduced as under:-

Location	The proposed site was located at Khewat No.320, Khatooni 416-419, Khasra No.23, Kot Mian Abdul Aziz, Post Office, Alla Abad, Tehsil Kamoke, District Gujranwala. The plot was not located in agricultureal area. Location map of the proposed site is attached, taken from the google maps at the time of visit, showing geographical coordinates (31.93181, 74.359319) for future reference.
Surrounding	• On the east side of the plot was road. • On the west side of the plot was agricultural land. • On the south side of the plot was agricultural land.

	• On the north side of the plot was agricultural land.
Size	The size of the plot is 6 Kanals approx. as per documents provided.
Recommendations	In the light of physical verification of site and scrutiny of documents provided by the applicant, **the proposed site is suitable for establishment of medical device manufacturing unit.**

Decision: The Board approved the site of M/s Kamoke Pharma Industries, Khewat No.320, Khatooni 416-419, Khasra No.23, Kot Mian Abdul Aziz, Post Office, Alla Abad, Tehsil Kamoke, District Gujranwala for establishment of manufacturing unit of medical devices.

Case No.3. M/s Adam Motors, DSU-II, Pakistan Steel Industrial Estate Bin Qasim, Karachi has informed that they are interested to install Manufacturing Unit for Medical Devices. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi and Awais Ahmed, FID, DRAP, Karachi were nominated for inspection of site verification. They have submitted following recomendations:-

Recommendations:

The inspection team visited the site of M/s Adam Motors at DSU-II, Pakistan Steel Industrial Estate Bin Qasim, Karachi reserved for establishment of manufactruing unit for medical devices on 8thOctober, 2019. The said site was covered plot, previously used for manufacturing of Adam Motors vehicles, besides the said premises, contract manufacturing of vehicle parts was being carried out. The has established manufacturing assembly and testing facility for proposed manufacuring of wheel chairs at the said site. **The location/surroundings are suitable to establish the manufacutring unit for manufacture of medical devices.**

Decision: The Board approved the site of M/s Adam Motors, DSU-II, Pakistan Steel Industrial Estate Bin Qasim, Karachifor establishment of manufacturing unit of medical devices.

Case No.4. M/s Human Care Pharmaceutical Industries Plot No. 131, Industrial Estate, Vehari has informed that they are interested to install Manufacturing Unit for Medical Devices. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Shahid Muhammad Iqbal, Assistant Director-III(MDMC) DRAP, Islamabad was nominated for inspection of site verification. Inspection report is reproduced as under:-

The site verification of M/s Human Care Pharmaceutical Industries was conducted on 29.11.2019 for the verification of site suitability with reference to Directorate of MDMC Letter No. F 12-165/2019-MD dated 27th November, 2019.

Location:

The site is located at Plot No. 131, Industrial Estate, Vehari. There is no residential or commercial area around this plot.

Size:

Total area/Size of the plot is about 0.631 Acre (Plot No. 131) allotted on lease agreement by the Punjab Industrial Estate Development and Management Company (PIEDMC) as per Lease deed issued in favor of M/s. Human Care Pharmaceutical Industries dated 07.08.2019.

Surroundings:

At present, the plot is away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of dust or smoke which may contaminate Medical Devices being manufactured or adversely affect on quality of Medical Devices. In future the owner of the company will be responsible. A detailed site plan along with undertaking has been submitted.

Recommendations:

The location is in newly established industrial area and surrounding of the premises complies with the general requirements for establishment to manufacture medical devices. **In view of the above facts the site is suitable for establishment to manufacture medical devices under the Medical Devices Rules, 2017, as of today** on the basis of Letter No. F 12-165/2019-MD dated 27th November, 2019 and documents submitted by the intended manufacturer. All the responsibility lies with the intended manufacturer regarding establishment to manufacture medical devices in the said plot as per GMP compliant facility.

Decision: The Board approved the site of M/s Human Care Pharmaceutical Industries Plot No. 131, Industrial Estate, Veharifor establishment of manufacturing unit of medical devices.

Item No.IV.<u>REGISTRATION OF MEDICAL DEVICES FOR EXPORT.</u>

M/s Renacon Pharma Limited, Lahore has applied on Form-7 for registration of following medical devices for export to Malaysia only:-

S.No	Name of Medical Device	Composition
1	**Hemocart** Hemodialysis Sodium Bicarbonate Cartridge ($NAHCO_3$, EP/BP)	Sodium Bicarbonate Powder BP/EP in granulated form.650, 720, 750, 1200, 1250grams
2	**HEMOSATE CT** (hemodialysis concentrate)' Part-A (powder) + Part-B (powder), for Bicarbonate Hemodialysis.	*Concentration of finally diluted & mixed solution (Part A+B=dialysate) in Haemodialysis machine for Registration :* **Part A** Sodium.....125-155 mmol/1 Potassium..... 0-3.0 mmol/1 Calcium..... 0-2.0 mmol/1 Magnesium..... 0-1.2 mmol/1 Chloride..... 90-120 mmol/1 Glucose..... 0-12.0 mmol/1 Citrate .....0.5-10 mmol/1 **Part-B (Powder)** Sodium.....Not more than45mmol/1 Bicarbonate.....Not more than 45mmol/1
3.	HEMOSATE PW (Hemodialysis Concentrate) Part-A (powder) + Part-B (powder) + Part-C (liquid) for Bicarbonate Hemodialysis	Formulation of Parts A, B & C for Registration Part A(as per BP/EP): Sodium.....80-110 mmol/1 Potassium..... 0-3.0 mmol/1 Calcium..... 0-2.0 mmol/1 Magnesium..... 0-1.2 mmol/1 Chloride..... 90-120 mmol/1 Glucose..... 0-12.0 mmol/1 Part B (as per BP/EP): Sodium.....Not more than 45mmol/1 Bicarbonate..... Not more than 45mmol/1 Part C (Acetum): Acetic Acid..... 2.5-10 mmol/1

The firm has submitted following documents:-

(i) Application on Form-7 alongwith prescribed fee.
(ii) Copy of purchase order.
(iii) Copy of valid Establishment License to manufacture medical devices.
(iv) Method of manufacturing.
(v) Indication, and functionality/usage.

The Authority has already approved Form-8C for issuance of registration/enlistment of medical devices for export only.

To facilitate the export of medical devices, registration letters for the above mentioned medical devices were issued.

Decision: The Board endorsed/ratified the registration letter issued by the MDMC Division for export of above mentioned medical devices.

Item No. V. <u>CHANGE OF TECHNICAL STAFF OF M/S AMSON VACCINES AND PHARMA (PVT) LTD, ISLAMABAD.</u>

M/s Amson Vaccines and Pharma (Pvt) Ltd, Islamabad applied for change of quality control incharge in their ELM-0005 as the existing quality control incharge has resigned from his post and requested for approval of new quality control incharge. The firm has submitted following documents.

(i) Form- 1 for change of technical staff
(ii) Resignation of existing QCI
(iii) Appointment/experience letter of new Quality Control Incharge
(iv) Copies of CNIC, educational documents, certificate of pharmacy council and photographs of new Quality Control Incharge.
(v) Requisite fee of Rs: 50000/-

The proposed changes in technical staff includes:-

Previously approved Quality Control Inchage	Proposed Quality Control Inchage
Mr Fiaz Arshad (Pharm-D)	Miss Shamim Ara (Pharm-D)

Decision: **The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Mr Fiaz Arshad (Pharm-D) to Miss Shamim Ara (Pharm-D).**

Item No. VI. CHANGE OF TECHNICAL STAFF OF M/S LASANI HEALTH CARE, GADOWN AMAZAI.

M/s Lasani Health Care, Gadown Amazai has applied for change of their Production Inchage and Quality Control Inchage. The firm has submitted all relevant documents alongwith prescribed fee of Rs.50,000/- and requested for alpproval of new Production Incharge and Quality Control Incharge as detail given below:-

Existing Production Incharge	**Proposed Production Incharge**
Muhammad Rashid (B.Pharm)	Mr.Inayat Ullah (Pharm. D)
Existing QC Incharge	**Proposed QC Incharge**
Mr. Muhammad Saleem (Msc. Chemistry)	Mr. Sana Ullah (Pharm-D)

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

Item No. VII. CHANGE OF MANAGEMENT AND TECHNICAL PERSON OF M/S OBS PAKISTAN (PVT) LTD.,KARACHI.

M/s OBS Pakistan (Pvt) Ltd., C-14, Manghopir Road, SITE, Karachi have requested for approval of change of particulars in their ELI No.00003, issued on 30-08-2019 as per detail given below:-

Existing Particulars	**Proposed Particulars**
Names of partners/proprietors/directors	
1. M. Arsalan Batla (CNIC.42201-7571901-7). 2. Mirza Anjum Fahim (CNIC # 24101-7618398-1). 3. Saeed-ur-Rehman (CNIC #16202-0938238-3).	1. Mr. Munis Abdulla (CNIC #42201-9982517-1). 2. Mst. Faiza Naeem (CNIC # 42201-0540338-0). 3. Mirza Anjum Fahim (CNIC # 42101-7618398-1). 4. Mr. Mudassir Habib Khan (CNIC # 42000-0528026-1) 5. Mr. Hammad Bin Kafeel (CNIC # 42101-1928271-9). 6. Mr. Tariq M Khan (CNIC #42301-0725070-1)
Name of Qualified Technical Persons	

Farzan Mazhar (CNIC # 42101-9526316-1)	Sagar Nehal (CNIC # 44302-3888759-3)

2. The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of new Drug Sale License.
(iii) Credentials of qualified person.
(iv) Fee of Rs.10,000/-
(v) Copy of Establishment License.
(vi) Undertaking on stamp paper from Senior Managing Director.

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

Item No. VIII. <u>CHANGE OF TECHNICAL PERSON OF M/S NOVATEK PAKISTAN, FAISLABAD.</u>

M/s Novatek Pakistan, P-20, 1st Floor, Office No.1, Channab Market, Susan Road, Madina Town, Faisalabad, has requested for approval of proposed change of their technical person in ELI-00454 as their existing technical person has resigned as per detail given below:-

Existing Technical Person as per Establishment License.	**Proposed Technical Person**
Miss. Aneela Adeeb, R/o Main Street, Chungi No.8, Lahore Road, Green Town, Chak No.445/EG, Tehsil Burewala, District Vehari. CNIC No.366011002417-6	Ms. Wajeeha Ashraf House No.46-P, Street No.4, Mohallah Ameenabad No.1, Tehsil & District Faisalabad CNIC No.33100-3483263-8

The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of new Drug Sale License.
(iii) Credentials of qualified person.
(iv) Fee of Rs.10,000/-
(v) Copy of Establishment License.
(vi) Undertaking on stamp paper from proprietor and technical person.

Decision: **The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Miss. Aneela Adeeb to Ms. Wajeeha Ashraf, CNIC No.33100-3483263-8.**

Item No. IX. CHANGE OF MANAGEMENT OF M/S B.BRAUN PAKISTAN (PVT) LTD., KARACHI.

M/s B.aun Pakistan (Pvt) Ltd., The Forum,uite 216, Khayaban-e-Jami, Clifton Block 9, Karachi have requested for approval of proposed change of their management in ELI-00006 as per detail given below:-

Existing Management	Proposed Management
1. Mr Sued Muhammad Zafar Hashmi (CEO), 50/A, Khayaban-e-Shaheen, Phase 5, DHA, Karachi, CNIC-42301-9658592-5.	1. Mr Sued Muhammad Zafar Hashmi (CEO), 50/A, Khayaban-e-Shaheen, Phase 5, DHA, Karachi, CNIC-42301-9658592-5.
2. Mr. Wasif Sajjad, House No. 4E, 11/5, Nazimabad, Karachi CNIC:42101-2332787-9.	2. Mr. Wasif Sajjad, House No. 4E, 11/5, Nazimabad, Karachi CNIC:42101-2332787-9.
3. Mr. Christian Joachim Rainer Hildebrandt, Apartment No.1E-15-12, Quayside Condominlum Sri Tanjung, Penang, 10470, Malaysia.	3. Mr. Senon Esermann, 521, D-2-1, TheCove, Jalan Tanjung Bungah, 11200, Penang, Malaysia.
4. Andreas Walde, The Cove D-33A-1, Jalan Tanjung, Bungah 112000 Tanjung Bungah, Penang, Malaysia.	4. Mr. Christoph Mueller, 1 Tanjong, 519B-21-2, Jalan Tanjung Bungah, 11200, Penang, Malaysia.

The firm has submitted following documents :-

(i) Application on Form-2.
(ii) Copy of Drug Sale License.
(iii) Fee of Rs.10,000/-
(iv) Copy of Establishment License.
(v) Copy of Certificate of incorporation.
(vi) Copy of Form-29.
(vii) Undertaking on stamp paper from CEO and technical person.

Decision: **The Board acceded to the request of the firm /company and approved the change of management as mentioned above.**

Item No. X. CHANGE OF TECHNICAL PERSON OF M/S IQBAL& COMPANY, ISLAMABAD.

M/s Iqbal & Company, Islamabad HAS applied for change of qualified person in their establishment license to import medical devices (ELI- 00117). The detail of previous and newly appointed technical staff is mentioned below:

Previous Technical Staff Details	New Technical Staff Details
Mr Ejaz Riaz CNIC No: 37405-8322153-9	Ms Sidra Razzaq CNIC No: 61101-9037151-2

The firm provided following documents for change of technical staff

1. Form 2 for change of qualified person
2. Copy of establishment license to import medical devices
3. Copy of CNIC, academic documents, experience certificates, photographs and registration certificate of Punjab pharmacy council of newly appointed qualified person
4. Requisite fee of Rs 10000/- for change in particulars in establishment license to import medical devices under Medical devices Rules, 2017

Decision: **The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Mr Ejaz Riaz to Ms Sidra Razzaq, CNIC No: 61101-9037151-2.**

Item No. XI. **CHANGE OF MANAGEMENT AND TECHNICAL PERSON OF M/S 3M PAKISTAN (PVT) LTD KARACHI.**

M/s 3M Pakistan (Pvt) Ltd Karachi has applied for change of qualified person and change of management in their establishment license to import medical devices (ELI- 00259). The detail of previous and newly appointed technical staff and management is mentioned below:

Previous Management Details	**NEW Management Details**
Jarri Masood Zaidi S/O Masood Ali Zaidi CNIC No: 42201-3462739-5	Nazar-Ur-Rehman S/O Saeed Ahmed CNIC No: 35202-1268811-9
Previous Technical Staff Details	**New Technical Staff Details**
Ms Naveen Mazhar Siddiqui CNIC No: 41303-6831916-4	Mr Muhammad Ather Latif Khan CNIC No: 36302-2802314-7

The firm provided following documents for change of technical staff

1. Form 2 for change of management and qualified person
2. Copy of establishment license to import medical devices.
3. Copy of new DSL mentioning new qualified person.
4. Copies of appointment letter qualified person.
5. Copy of CNIC, academic documents, experience certificates.
6. Requisite fee of Rs 10000/- for change in particulars in establishment license to import medical devices under Medical devices Rules, 2017.

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

Item No. XII. <u>CHANGE OF NAME OF LEGAL MANUFACTUREROF REGISTERED MEDICAL DEVICES</u>

M/S Digital imaging has stated that the legal manufacturer of below mentioned registered product has changed its name from **M/S AGA medical Corporation 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442** to **M/SAbbott Medical 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442**. For that purpose the firm has submitted following documents

1. Original notarized letter from legal manufacturer mentioning the reason for change of name
2. Embassy attested original free sale certificate mentioning new name of manufacturer
3. Notarized full quality assurance certificate
4. Notarized ISO 13485 of legal manufacturer
5. Fee of Rs. 25000/- for each product
6. Declaration of conformity of

and requested to change the name of legal manufacturer of below mentioned products:-

S. No.	Name of Medical Device	Previous Legal Manufacturer	Newly Proposed Legal Manufacturer	Codes
1.	**Amplatzer Duct Occluder II**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000450
2.	**Amplatzer Duct Occluder**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000454
3.	**Amplatzer Vascular Plug**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000456

4.	**AMPLATZER SEPTAL OCCLUDER**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000444
5.	**Amplatzer TorqVue Delivery System**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000451
6.	**Amplatzer TorqVue Exchange System**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000449
7.	**Amplatzer TorqVue LP Catheter**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000793
8.	**Amplatzer TorqVue LP Delivery System**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000452
9.	**Amplatzer Multifenestrated Septal Occluder Cribriform**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000447
10.	**Amplatzer Guidewires**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000446

		55442		
11.	**Amplatzer PFO Occluder**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000448
12.	**Amplatzer Sizing Balloon**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000445
13.	**AMPLATZER MEMBRANOUS VSD OCCLUDER**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000455
14.	**AMPLATZER MUSCULAR VSD OCCLUDER**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000453
15.	**AMPLATZER P.I MUSCULAR VSD OCCLUDER**	**AGA Medical Corporation** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	**Abbott Medical** 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442	As per previous registration number MDIR-0000457

Decision: The Board discussed the matter at length and approved the new legal manufacturers of above mentioned medical devices as mentioned against each.

Item No. XIII. <u>CHANGE OF BRAND NAME 'LIBIDO' OF M/S HSB INNOVATION IN HEALTH.</u>

M/s HSB Innovation in Health, Lahore product, namely, LIBIDO (contraceptive device) was approved subject to change of name. The importer has stated that they cannot change their brand name of product 'Libido' because they are in business from 2004 and their brand name is also registered as trade mark since 2004. Their brand name has been established in the market for 15 years, so they cannot change their brand name of the product due to their total loss of goodwill, brand and business.

Decision: The Board acceded to the request of the firm to the retain the name of their contraceptive device LIBIDO.

Item No.XIV.<u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD</u>.

The MDB in its different meetings considered and approved the following medical devices of M/s Optisurg subject to inspection abroad:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s Optisurg 17/C-1, Valancia Town, Lahore (ELI-00305) **(M-11)**	**Legal Manufacturer/ Manufacturer:** M/s Hoya Medical Singapore Pte. Ltd. 455A Jalan Ahmad Ibrahim 639939, Singapore (FSC Singapore Valid Till 07-08-2020)	Hoya-PS AF-1 Hoya Preloaded System Intraocular Lens Class C Shelf Life: 3 Years Model: PC-60R, PY-60R Fee submitted: Rs 50,000/-	The Hoya-PS AF-1 is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secretary is authorised to issue Registration Certificate on panel of inspectors recommendation.
2.	-do- **(M-11)**	-do-	Hoya Vivinex iSert Preloaded Intraocular Lens Class C Shelf Life: 3 Years Model:XY1 XC1 Fee submitted: Rs 50,000/-	The HOYA Vivinex™ iSert® IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens	-do-
3.	-do- **(M-11)**	-do-	Hoya iSert Preloaded Intraocular Lens	The HOYA iSert® IOL is intended to be placed into the	-do-

			Class C Shelf Life: 3 Years Model: 150, 151, 250, 251 Fee submitted: Rs 50,000/-	capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens	
4.	-do- **(M-11)**	-do-	Hoya Vivinex Toric Preloaded Intraocular Lens Class C Shelf Life: 3 Years Model: XY1AT2, XY1AT3, XY1AT4, XY1AT5, XY1AT6, XY1AT7, XY1AT8, XY1AT9 Fee submitted: Rs 50,000/-	The HOYA Vivinex Toric IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens	-do-

Meanwhile, the firm has provided the Free Sale Certificate of Germany for the products at Sl.No.1-4.

Decision: The Board considered that the firm has provided the Free Sale Certificate of Germany for the above four (4) products and acceded to the request of the firm for exemption of inpsection of manufacturer abroad.

Item No.XV.<u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABOARD</u>.

The MDB in its 14th meeting held on 11-10-2019 considered and approved the following medical devices of M/s Wasim Co., subject to inspection abroad:_

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
	M/s WasimCo., KutchiGali No.1, Marriott Road Karachi.	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co.,	Classic Fine Disposable Hypodermic Needle, Sterile. Class B	Sterile Hypodermic Needles for Single Use is a Sharp, hollow instrument that connects to a syringe and is	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.

	(ELI-00185)	Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China.	Shelf Life: 5 Years. Size: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G,	commonly used to inject liquid drugs or medications directly into the skin (Under the dermis) or into a vessel or sometimes for extracting blood.	

Meanwhile, the firm has provided the **Free Sale Certificate of Germany** for the above mentioned medical devices which is a reference country and exempted from inspection.

Decision: The Board considered that the firm has provided the Free Sale Certificate of Germany for the above mentioned medical devices and acceded to the request of the firm for exemption of inpsection of manufacturer abroad.

Item No.XVI.IMPORT OF SURGICAL SUTURES/HYPODERMIC NEEDLES..

Case No.1.

Assistant Director/FID-IX, DRAP, Karachi has stated that M/s Nishat Surgical, Office No.A-114-296, Jail Road, Hyderabad has applied for issuance of clearance certificate for import of following surgical sutures vide Invoice No.IHA2019000000100 dated 30th October, 2019 imported from M/S Dogsan Tibbi Malzeme san, a.s. Turkey:-

S.No.	Name of Suture (medical device)	Registration No.
1.	Popilen 5/0 13 3/8 Round Bodied Popilen 4/0 Round Bodied Popilen 2/0 30 Round Bodied Popilen 4/0 25 Round Bodied Propilen 7/0 Round bodied	090758
2.	Pedesente 1 40 1/2 Round bodied Pedesente 5/0 Round bodied Pedesente 1 40 Round bodied	090762
3.	Pegelak 4/0 Round bodied Pegelak 2 40 Round bodied Pegelak 2 45 Round bodied Pegelak 2/40 Round bodied Pegelak 2/0 Round bodied Pegelak 1 40 Round bodied	090760
4.	Silk 0 30 1/2 Round bodied	090759

	Silk 1 30 1/2 Round bodied Silk 3/0 Round bodied	

He further stated that during scrutiny of the cases, it was revealed that Establishment License (Form-4) is not submitted alongwith the case, however, the importer has applied for the same in DRAP Islamabad in September, 2019. Assistant Director/FID-IX, DRAP, Karachi has requested for necessary guideance for disposal of the case, as the firm has applied for establishment license as well as the products are registered and case is conditionallyy released "sale of restricted" on the direction of Additional Director, DRAP, Karachi.

In this regard, it is submitted that M/s Nishat Surgical, Office No.A-114-296, Jail Road, Hyderabad has applied for grant of an establishment license to import medical devices and a panel has already been constituted for inspection of the firm. Furthermore, the firm has valid registration of above mentioned medical devices (registered as drug). The case is placed before the MDB to allow the utilization / sale of said medical devices.

Decision: The Board discussed the matter at length and considering that the firm previously did not have the Establishment Licence to Import Medical Devices as it was not required, therefore, allowed the firm M/s Nishat Surgical Office No.A-114-296, Jail Road, Hyderabad to utilize the above mentioned products, earlier registered as drugs. The Board also authorized the Secretary MDB to allow utilization of imported products and get it ratified / approved from the Board in future.

Case No.2.

Assistant DirectorDRAP, Karachi has stated that M/s Batla Impex, 40, Namco Centre, Campbell Street, Karachi has applied for issuance of clearance certificate for import of **Golden Plus Sterile Hypodermic Needles** vide Invoice No.CZKFL 191111 dated 11th November, 2019 imported from M/S Changzhou Kanmgfulai Medical Thing Co Ltd., China.

He further stated that during scrutiny of the cases, it was observed that the firm has been granted Establishment License (Form-4)and the firm has applied for the regisration of above product in DRAP, Islamabad in October, 2019. Assistant Director/FID-IX, DRAP, Karachi has requested for guidance/direction for disposal of the case.

Decision: The Board discussed the matter at length and directed Assistant Director / FID-IX, DRAP, Karachi to release the consignment with restriction on use unless the products are registered by the MDB.

ITEM NO.XVII. <u>ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/S B.BRAUN PAKISTAN (PVT) LIMITED, KARACHI.</u>

M/s B.Braun Pakistan (Pvt) Limited, Karachi has requested to grant them 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-0000546	Spinocan (Needle For Spinal Anaesthesia)	**Legal Manufacturer:** M/s B.Braun Melsungen Ag, Carl-Braun-Strade 1, 34212, Melsungen, Germany. **Manufacturing Site**: M/s B.Braun Medical Indusries Sdn. Bhd, Bayan Lepas Free Industrial Zone 11900 Penang, Malaysia.	4501144, 4501195,4501373, 4501900, 4501918,4502140, 4502906,4503902,4505751, 4505905,4506014,4507401, 4507754,4507908,4509757, 4509900,4504917, 4505913,4506090.	4501390 (As per Free Sale Certificate of Germany)

The firm has deposited fee of Rs.25,000/- and has given application on Form 7-A. Firm has also submitted a valid and original and Embassy attested Free Sale Certificate of Germany mentioning the requested additional codes.

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

ITEM NO.XVIII. <u>ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/SKOHSAR DISTRIBUTORS, RAWALPINDI.</u>

It is submitted that M/s Kohsar Distributors, Rawalpindi had requested to grant them additional size of their following registered imported medical devices (registered as drug) as mentioned below:-

S. No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.	Name of Manufacturer
1.	069511	Paramount Syringes	1ml 2ml 5ml 10ml 20ml	3ml	M/s Jiangsu Kangyou Medical Instrument Co., Ltd, Tangzuang, Yaotang Town, Jintan City, Jiangsu Province, China.

The firm has submitted following documents:-

Fee challan of Rs.5000/- for each product.

(i) Copy of registration letter of each product.
(ii) Copy of Drug Sale License.
(iii) Original Free Sale Certificates by SFDA China (Embassy attested) mentioning 3 ml size of syringes.

After scrutiny of the papers, the firm was asked to provide stability study of additional pack size i.e. 3ml for further processing the case. It is submitted that due to finalization of amendments in Medical Devices Rules, the case was not processed further. Now, M/s Kohsar Distributors, Rawalpindi have submitted relevant documents.

Decision: The Board acceded to the request of the firm /company and approved the additional size of 3ml of Paramount Syringes (Reg.No. 069511) subject to provision of stability studies.

Item No.XIX. <u>INCREASE IN SHELF LIFE.</u>

It is submitted that M/s Atco Pharma International (Pvt) Limited, Karachi has requested for extension in shelf life from 3 Years to 5 years of their already registered following imported medical device (Registered as Drug):-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
MDIR-0000080	Fluydo Pegaso PTCA Balloon Catheter Balloon Length (mm): 10, 15, 20 & 30. Balloon Dia (mm):	**Manufacturer:** M/s CID S.p.a, Strade per Crescentino s/n 13040 Saluggia, Italy. **Manufacturing Site**: M/s Alvimedica Tibbi, Urunler San. Ve Dis Tikaret A.S	3 Years	5 Years

	1.5, 2.0, 2.5, 3.0, 3.5 & 4.0.	Istanbul Trakya Serbest Bolgesi Ferhatpasa Mah. Ataturk Bulv, Manolya Sok. No.7, 34540 Catalca-Intanbul, Turkey.		

The firm has submitted following documents:-

(i) Fee Deposited Rs.25,000/-
(ii) Copy for five years shelf life validation report.
(iii) Copy of validation of packing report.
(iv) Copy of stability for sterility test.
(v) Copy of registration certificate.
(vi) Copy of establishment licence to import medical devices.
(vii) copy of DSL.

Decision: The Board acceded to the request of the firm /company and approved the shelf of the Fluydo Pegaso PTCA Balloon Catheter (Reg.No. MDIR-0000080) from 3 years to 5 years.

Item No. XX.EXTENSION IN SHELF LIFE.

M/s Digital Imaging Systems, Lahore has requested for extension in shelf life from 01 Year to 02 years of their already registered following imported medical device (Registered as Drug):-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
083404	Graft Master RX Coronary Stent Graft System	**Legal Manufacturer:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Site**: M/s Abbott Vascular Cashel Road Clonmel, Co. Tipperary, Ireland	01 Year	02 Years

The firm has submitted following documents:-

(i) Fee Deposited Rs.25,000/-
(ii) Application on Form 7-A
(iii) Aging Evaluation Report supporting 24 Months Shelf Life.
(iv) Registration Certificate issued by India for the above stated Medical Device mentioning 24 Months Shelf Life.

Decision: The Board acceded to the request of the firm /company and approved the shelf of the Graft Master RX Coronary Stent Graft System (Reg.No. 083404) from 01 year to 02 years.

ITEM NO. XXI: <u>REGISTRATION AS AN INDENTER UNDER RULE 72(1) OF MEDICAL DEVICES RULES, 2017.</u>

In the 14th Meeting of MDB, the submission of M/s Muller & Phipps (Pvt) Ltd was made as under:

"M/s Muller & Phipps (Pvt) Ltd has submitted an application addressed to Additional Director (MD&MC) / Secreatary MDB requesting for Registration as an Indenter under Rule 72(1) of Medical Devices Rules, 2017. The extract of the letter is as under:

"We carry out all kind of operations for Johnson & Johnson Pakistan (Pvt) Ltd. As an authorised representative related to Marketing, Import, Sales, Storage& Distribution for their complete range of products from last many years. Johnson & Johnson authorized M&P as distributor / indenter for importation of medical devices (see enclosed).

That Rule 72(1) of the Medical Devices Rules, 2017 states that medical devices may be imported through an indenter registered by the MDB. Muller & Phipps intends to import medical devices on behalf of M/s Johnson & Johnson as an authorize agent / distributor in Pakistan in order to ensure the continuous availability and accessibilioty of quality products for the patients & health care professionals. We request you to register us an an indenter for import of J&J medical devices on the basis of our long experience and fulfilling compliance requirements entrusted us by the Medical Device Board DRAP vide issuing Form-4.

We, Muller & Phipps Pakistan being medical devices importer and indenter shall be responsible to follow the essential principle of safety & performance of medical devices and complies with post market surveillance and any regulatory matter if ask by the MDB. We also take full responsibility for post marketing surveillance and pharmacovigilance system under guidance of Johnson & Johnson technical team and as per Medical Devices Rules requirements."

In 13th Meeting of MDB held on 05-08-2019, Muller & Phipps Pakistan (Pvt) Ltd made a similar request which was placed before the MDB for decision but was deferred due to comments / opinion of Dr. Abdul Haleem Khan, member MDB. The case along with decision is herein below:

M/s Muller & Phipps Pakistan (Pvt) Limited has a Multinational Distribution Network for National and Multinational Pharmaceutical Manufacturer as well as legal importer of drugs and

medical devices. They have broad range of innovative products and solutions in their portfolio and are fully conversant with vast experience to cater import, storage and distribution of medical devices.

The firm has requested for registration as an Indenter for import of medical devices and has referred to the Rule 72 (1) of Medical Devices Rules, 2017 (MDR, 2017) whereby Medical Device Board (MDB) can register an Indenter. The Rule 72 of MDR, 2017 is reproduced as under:-

"Indenting of Medical Devices. *— (1) The medical devices may be imported through an indenter registered by the MDB.*

(2) Where an institute, hospital, a registered charitable trust or institution intends to import medical devices through an indenter, the MDB may allow such indenting subject to the condition that such medical devices imported through indenting shall not be sold for commercial purpose in the open market."

In view of the above, it is submitted that the conditions/pre-requisites for registration of Indenter has not been prescribed in the MDR, 2017. The following conditions for registration of Indenter are proposed for consideration of MDB:-

CONDITIONS FOR REGISTRATION OF INDENTER

DEFINITIONS:-

Indent:

Order of goods (placed trough a local or foreign agent of a foreign supplier) under specified conditions of sale, the acceptance of which by the supplier (or the agent) constitutes a contract of sale.

Indenter:

A person possessing a valid licence to import medical devices (Form-4), representing as an authorized agent of a foreign company, product, and who gets commission or royalty on any transaction which takes place in his home country.

CONDITIONS:

(i) In case of commercial import, the indenter and a person or facilitator to whom an indent be issued shall both possess a valid licence to import medical devices on Form-4.

(ii) In case of an hospital, a registered charitable trust or institution intending to import medical device through an indenter, the person to whom indent is issued shall possess a valid licence to import medical devices on Form-4.

(iii) The indenter shall possess the enlistment or registration certificate of a medical device issued on Form-8 and Form-8A respectively by the MDB as the case may be.

(iv) The indenter shall be solely responsible for the quality, safety and performance of medical devices for which an indent has been issued.

(v) The indenter shall ensure that a person to whom an indent is issued has the specified storage facility for the medical device along with specialized team for the supervision /vigilance of Post Marketing Surveillance (PMS) of the product so that timely recall, return, withdrawal, field safety & corrective action (FSCA), etc., can be taken.

(vi) The indenter shall issue a warranty of an imported medical device as provided in Medical Devices Rules, 2017.

(vii) Both the indenter and to whom an indent has been issued shall ensure that all government taxes and duties are being paid.

(viii) The indenter shall be registered as an indenter for a period of one year on making an application addressed to the Director, Medical Devices &Medicated Cosmetics (MDMC) along with submission of fee challan of Rs.50,000/-.

INDENT #

Date:

PROFORMA INVOICE #: Origin:

SELLER : BUYER:

Quantity	Packing	Descriptions	Unit Price C & F	Total Amount
			City BY AIR/SEA	

Payment :

Shipment upto: Negotiation upto: _____

From: Shipping Marks:

CONDITIONS / INSTRUCTIONS

- Please comply Bank contracts conditions, & send one complete set of non-negotiable shipping documents to us and as to opener immediately after shipment.
- Kindly mention product description on each carton.
- Warranty under Medical Device Rules, 2017. Warranty void if packing is altered

I, _____, being a person resident in Pakistan carrying on business (full address) _____under the name_____ holding valid licence No. _____ issued by _____and having authority or being authorized by M/s (full address) _____, authorized vide letter No. _____dated _____, do hereby give this warranty that the medical devices described as sold/indent by me and contained in the bill of sale, invoice, bill of lading or other document describing the medical devices referred to herein do not contravene in any way the provision of the DRAP Act, 2012 and the rules framed there-under.

Signature

BANK DETAILS:

SWIFT CODE:

Buyers Signature For ***Indentor***

Decision: MDB discussed the matter at length. Mr. Abdul Haleem Khan, member MDB asked for time to study the matter in depth and would forward his opinion. The opinion received through email is reproduced as below:

In pursuance of 13th meeting Medical Devices Board held on August 5, 2019, ***I would like reaffirm my comments in respect of Agenda Item XVI titled " Registration as an Indenter under Rule 72 (1) of Medical Devices Rules, 2017*** *and these are detailed below:*

1. The request of the firm has no logical sense as all the Sole Agent / Authorized Distributor of Foreign Manufacturer /Principal in Pakistan are dully entitled to import the medical devices by placing an indent /purchase order to its Foreign Manufacturer / Principal as per laidown procedure, meaning Sole Agents / Authorized Distributors of Foreign Manufacturer /Principal in accordance with true spirit of Medical Devices Rules, 2017

2. Moreover, if any Foreign Manufacturer /Principal is licenced in Pakistan, it should indent/import its products into Pakistan by itself instead of any other firm/commercial party.

Keeping in view the above mentioned facts, I am of the opinion that the request of the firm may be rejected and or deffered for re-consideration in the meeting of MDB afterwards.

Accordingly, the Registration of an Indenter under Rule 72(1) of Medical Device Rules, 2017 is deferred.

After the finalization of the minutes the following comments / opinion of Prof. Dr. Sajid Bashir was also received to include in 13th MDB meeting:

Refer to delibration made in 13th MDB meeting and above said facts and discussion, In my Opinion:-

a) *It is the Power of Federal Government to make rules for Indent under Section 43(1) of the Drugs Act, 1976.*
b) *Under section 23 of the DRAP Act, 2012, Authority, with the approval of Federal Government, may make rules for carrying out the purposes of the Act.*
c) *Furthermore, under rule 72 of MDR, 2017, such provision of indenting is specific to charitable or non-profit purposes and cannot of sold commercially. M/s Muller & Phipps has applied as commercial indentor. Therefore, does not comes under the scope of said rules.*
d) *In addition to Facts Stated by worthy Dr. Haleem Khan, Member MDB, I would further like to add that Federal Government is also taking measures for Taxation and matters related to flow of cash in line with Financial Action Task Force recomendation. Therefore, this matter should also be referred to Finance Division and Ministry of Law & Justice to seek their opinion and legal obligations.*

Therefore, on such ground I am off the opinion that we may refer the matter to Authority to prescribe condition for indenting for all therapeutic goods including framing of rules approved by Federal Government after consultation with Finance Division & Ministry of Law & Justice. Till such time we may deferred the application of M/s Muller & Phipps.

Accordingly the case was placed before the MDB in its 14th meeting for consideration and deferred the case. Decision of MDB is reproduced as under:-

> *"Two MDB members, namely, Dr. Abdul Haleem Khan and Prof. Dr. Sajid Bashir who had reservations regarding indenting were not present in the meeting due to their pre-occupation, therefore the matter was deferred for discussion in coming MDB meeting."*

The decision of the MDB was conveyed to M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi.

M/s Johnson & Johnson Pakistan (Pvt) Ltd., have stated that as a follow up of their meeting on 8th October, 2019 with CEO DRAP, they are requesting for permission to continue to import medical devices products into Pakistan via their two distributors (i) Global Marketing Services for their Cardiovascular and Speciality Solutions business and (ii) Muller and Phipps for their Ethicon and DePuy Synthes business, until such time as the indenting registration procedure is clear under Medical Devices Rules, 2017.

They have elaborated that Johnson & Johnson Pakistan (Pvt) Ltd., a subsidiary of Johnson & Johnson, is one of the oldest and leading medical devices company's in Pakistan. Johnson & Johnson is one of the most innovative and comprehensive healthcare company having more than 250 offices located 60 countries around the

world with a legacy over 80 years pioneering Suture Technology. Johnson &Johnson is the only company to provide Triclosan coated sutures which reduce the risk of surgical site infections, since 1965 to meet the needs of an emerging and thriving nation of Pakistan.

Johnson & Johnson medical devices business segment produces a broad range of innovative products and solutions used primary by health care professionals in the fields of orthopedics, neurological disease, vision care, infection prevention, diagnostics, cardiovascular disease, and aesthetics. The J&J medical devices portfolio in Pakistan encompasses 20,000 products (skus) included in over 170 submission. The devices which are currently marketed in Pakistan are of all Risk Classes as defined in Reference Country's legislative framework (i.e. EU, USFDA, TFA, Health Canada and Japan) in accordance with Pakistan Medical Devices Rules, 2017 and are fully in line with medical device legislative framework. Johnson & Johnson Pakistan (Pvt) Ltd ensures the quality and compliance of all products as follows:-

(i) Johnson & Johnson Pakistan (Pvt) Ltd has a regulatory affairs team with scientific backgrounds that are responsible for preparation of the technical documentation provided to DRAP to register the product and have the appropriate qualifications to maintain oversight of the marketing authorization to ensure that all regulatory requirements are met as per DRAP's expectations.

(ii) Johnson & Johnson Pakistan regulatory affairs team has a reporting structure into the Middle East Regulatory Affairs team with a close connection to the legal manufacturers to ensure continued focus on technical specification, quality and compliance.

(iii) Johnson & Johnson Pakistan maintains distribution and quality agreements with Global Marketing Services and Muller and Phipps with oversight of quality issued by the J&J Pakistan regulatory affairs team and J&J Middle East Quality Team.

The process of importing a product does not bear any safety issues from a regulatory perspective and this current business model is appropriate based on the size of the market, political and currency situation. It allows them to continue to provide products to patients in Pakistan at a reasonable price while maintaining profit margins. Additionally, it allows for "checks and balances" to ensure the right individuals with the right skill set are responsible for the appropriate actions to ensure continued compliance.

Johnson & Johnson is committed to delivering safe and effective products to patients in Pakistan. J&J take strong pride that the people of Pakistan trust the name Johnson & Johnson and have entrusted us to provide 70% of the market leading products in Pakistan and want to continue well into the future, but the right business model conditions.

They have requested for approval to continue to import product for such a time the indenting registration procedure is clear so that we may continue to serve Pakistani patients with high quality medical devices."

Representative from J&J has also been invited to brief the MDB on issue of indenting.

Decision: The Board discussed the matter at length and then invited Mr. Ayman Ateyeh, head of Regulatory Affairs, J&J, Pakistan and Mrs. Mirette Abskharoun, Regulatory Affairs Manager, J&J (Middle East) Inc. to make power point presentation before the Board. The arguments put foreard by representatives of M/s J&J were mainly:

i) **M/S J&J is following Distributor Model in many countries such as Qatar, Kuwait, Bharain and Oman and the import of their products is being carried out through indenting via a third party. Under current economic conditions of Paksitan, this model suits M/s J&J for their business in Pakistan.**
ii) **M/s J&J has a technical team on ground in Pakistan to look after the regulatory affairs and post marketing surveillance issues for their products.**
iii) **M/s J&J referred to Rules 72(1) of Medical Devices Rules, 2017 whereby indenting is allowed.**

The Board members were of the following opinion:

a) **M/S J&J Pakistan has got the Establishment Licence to Import Medical Devices and have their registered products, therefore, they should import themselves rather than through a third party.**
b) **Import through indenting or third party involves a two step profit and if M/S J&J imports itself, then there will be higher margin of profit, which will bring down the price of their medical devices and the firm has more potential for expansion of their business in Pakistan. Additionally self import by the firm will benefit Pakistan's patients.**
c) **Self import by M/s J&J Pakistan will be easily manageable by keeping human resource and technical and financial team, which will ultimately booste the economy of Pakistan.**
d) **The Board was of the opinion that Rule 72(1) should be read with Rule 72(2) where indednting is allowed for only an institute, hospital, a registered charitable trust or institution.**
e) **The Board advised the M/s J&J to import their medical devices through indenting or third party by taking permission from Medical Devices Division**

under Rule 72(2) for an institute, hospital, a registered charitable trust or institution.

ITEM NO. XXII: VIOLATION OF LABELING REQUIREMENTS ON ACCU-CHEKACTIVE STRIPS OF M/S ROCHE PAKISTAN LIMITED.

A complaint was received on Pakistan Citizen Portal from Mr. Muhammad Aajiz Saleem against M/s Roche Pakistan Limited, for violation of labeling requirements on Accu-chek Active strips.

An action was initiated through QA&LT division who directed Additional Directors Lahore, Karachi, Islamabad, Peshawar and office in-charge Quetta for through evaluation and investigation in the matter. In continuation FID Peshawar, visited M/s Ali Gohar & Company Peshawar and seized the following stock.

S.No.	Name of Device	Batch No.	Marketed by	Quantity
1	Accu-Chek Active 2×50 strips	26002831	M/s Roche Pakistan Limited	2×2×50 strips
2	Accu-Chek Active 25 strips	24698723	M/s Roche Pakistan Limited	2×25 strips
3	Accu-Chek Active 50 strips	26000931	M/s Roche Pakistan Limited	2×50 strips

The firm was informed through FID Peshawar and their response is as under "We Roche Pakistan Limited having Establishment License # ELI 00009, already applied for the registration of above mentioned products according to Medical Device Rules 2017, which are still in implementation phase. We will start the process of MRP printing along with other requirement like printing of establishment license and product registration number etc, once products are registered. Considering the above mentioned explanation, it is requested to release above mentioned stock for sale to ensure smooth supply of blood glucose strips for diabetes patients. We again assure you that we will fully comply with the Medical Device Rules 2017 once registration is granted of mentioned products by DRAP".

The M/s Roche Pakistan Limited was granted registration of Accu-Chek Active strips dated 20-11-2019 vide registration number MDIR-0000914. The FID Peshawar has requested MDB for permission to keep the mentioned products under safe custody. Furthermore, the firm has advised to appear before the MDB for personal hearing.

Decision: **The Board discussed the matter at length and authorized the FID, Peshawar to release the above mentioned seized stocks subject to physical verification of the stock conditions and expiry. The Board directed the firm to print MRP and comply with the other conditions of labeling by printing in their licenced premises.**

The Board also advised the representative of the HDAP to request importers to comply with the condition of labeling with a period of 30 days, after which the Provincial Health Department will be requested to seize and take non-compliance stocks of medical devices in their custody.

Item No.XXIII. **EXEMPTION FROM INSPECTION ABROAD.**

The MDB in its 12th meeting held on 13-05-2019 decided that the following products of M/s the Searle Company Limited, Karachi are approved subject to inspection abroad:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description
1	M/s The Searle Company Limited, 1st Floor, NICL Building, Abbasi Shaheed Road, Karachi (ELI-00057) Evaluator: Muhammad Ayub Naveed	**Manufactured By:** M/s Abu Dhabi Medical Devices Co, L.L.C Mussafah City M43 –Block 124, P O Box 30485, Abu Dhabi, UAE (FSC UAE Valid Till 23-01-2019) **Fee. submitted Rs. 25000/-**	Medco® Inject Single Use Syringe 10ml Class B Shelf Life: 3 Years	Sterile Hypodermic Syringes
2	-do- Evaluator: Unum Zia Shamsi	**Manufacturer/Manufacturing site:** M/s Abu Dhabi Medical Devices Co, L.L.C Mussafah City M43 – Plot 124, P O Box 30485, Abu Dhabi, UAE (FSC UAE Valid Till 27-12-2020) Fee submitted Rs.25000/-	Medeco® Inject Re-use Prevention Syringe Class B Shelf Life: 3 Years 2/3 ml and 5 ml	Re-Use Prevention Syringes

The board decision is reproduced as under:

Decision: **Approved** subject to foreign inspection of the manufacturer abroad. The Board also authorized the Secretary, MDB to issue registration letter if the manufacturing plant is approved by the expert panel.

Meanwhile, the firm has provided the **Free Sale Certificate of Belgium** for the aforementioned products. Belgium is included in those countries for which inspection is exempted if the product is exported to it.

Decision: The Board considered that the firm has provided the Free Sale Certificate of Belgium for the above mentioned medical devices and acceded to the request of the firm for exemption of inpsection of manufacturer abroad.

Item No.XXIV.ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

Secretary MDB informed the Board that the following applications for grant of enlistment of medical devices for import on prescribed form 6-A under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/ Shelf Life	Brief Description	Decision
1.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi. ELI-00020 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	**One Piece Guedel Airway** Codes: 1115120S – Guedel Airways, size 5, ISO 12 1114100S– Guedel Airways, size 4, ISO 10 1113090S– Guedel Airways, size 3, ISO 09 1112080S– Guedel Airways, size 2, ISO 08	Used to provide an open airway and maintain a gas pathway through the oral cavity and pharynx. Sterile	**Approved.**

			1111065S– Guedel Airways, size 1, ISO 6.5 1110055S– Guedel Airways, size 0, ISO 5.5 1100050S– Guedel Airways, size 00, ISO 05 1000035S– Guedel Airways, size 000, ISO 3.5 Class A Shelf Life: 05 years Fee submitted: Rs. 5,000/-		
2.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Block 3, MCHS, Shaheed-e-Millat Road, Karachi (ELI-00274) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s Grifols Diagnostic Solutions Inc., 4560 Horton St, Emeryville, CA 94608, USA **Manufacturing Site:** M/s 401 Millcreek Road, Marietta, OH 45750-4304, USA (FSC USFDA Valid Till14-05-2020)	Procleix Reagent Preparation Incubator (RPI) 250 Class A Life expectancy: 20 Years Fee submitted: Rs. 5,000/-	A microprocessor-based, temperature-controlled chamber that automates the reagent preparation steps required for Procleix assays	**Approved.**
3.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s Hologic Inc. 10210 Genetic Center Drive, San Diego, CA 92121, USA (manufactured for Grifols Diagnostic Solutions Inc.) **Manufacturing Site:** M/s Neuwiesenstrasse 4, 8222 Beringen,	Procleix Panther System Class A Life expectancy: 20 Years Fee submitted: Rs. 5,000/-	An integrated nucleic acid testing system which fully automates all steps necessary to perform Procleix Assys from sample processing through amplification, detection and data reduction	**Approved.**

		Switzerland (FSC US FDA Valid Till 14-05-2020)			
4.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer :** Ljngberg&Kogel AB, Abelko, Industrivn 17, 97254 lulea, sweden **Manufacturering Site :** Albelko Innovation, Industrivagen 17, SE-972 X54X Lulea, Sweden. (FSC Valid 25-05-2020)	Biosealer CR4 AA, CR6 AA, CR6-PS AA Biosealer Class-A Shelf Life: 10 year operating life Codes: Biosealer CR4 AA With Bench Unit CR4AAb Biosealer CR4 AA with ergonomic sealing handle CR4AAes Biosealer CR4 AA with sealing handle CR4AAs	Biosealer CR4 AA is built for sealing PVC tubes, specially blood bags tubes or sets for plasmaferes. It has a powerful HF-unit (High frequency), which makes it suitable both for routine procedures at donation rooms and repeated operations at preparation rooms without overheating.	**Approved** subject to provision of Full QA certificate.
5.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer :** Ljngberg&Kogel AB, Abelko, Industrivn 17, 97254 lulea, sweden **Manufacturer Site:** Albelko Innovation, Industrivagen 17, SE-972 X54X Lulea, Sweden. (FSC Valid 25-05-2020)	Biomixer 323-1, 330-1 Biomixer Class –A Shelf Life: 10 Years service life Codes: Biomixer 323-1 Biomixer 330-1	Biomixer 323-1, 330-1 are used for collection of blood at stationary and mobile donor centers. The mixer is preset at certain collection volume before start of collection. When the collected blood has reached the set value, the tube to the blood bag is automatically sealed by a clamp. During transport between	**Approved** subject to provision of Full QA certificate.

				the facilities, the mixer is stored inside a bag specially designed for the mixer.	
6.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Genesis BPS LLC, Located at 465 StateRt 17, Ramsey, NJ 07446, USA. (FSC Valid 28-11-2020)	Genesis (Sterile Tube Welder) Class-A Shelf Life :10 years Service life Codes: TCDB40	The genesis Rapid Weld STW was developed for the purpose of connecting blood product containers via tubing without opening the system and compromising the sterility of contained fluids. This is not the sterile device	**Approved.**
7.	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi (ELI-00240) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Huaian City Tianyi Medical Instrument Co., Ltd. No. 123 Meicheng Road, Qingpu District Zone, Huaian, City Jiangsu, China. (FSC China valid till 24-12-2020)	GB Urine Drainage Bag Class A Size: 2000ml Shelf Life: 5 Years Fee submitted: Rs 5,000/-	Sterile disposable urine drainage bag	**Approved**.
8.	M/s. Haji S. Ameer Din & Sons, 305-A, Upper Mall, Lahore. ELI-00059 **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: UNICOS Co, Ltd. 282-30, Munji-ro, Yuseong-Gu Daejeon,Korea FSC Korea issue date 08-04-2018	Unicos UDR-800 (Digital Refractor) Class A Service life: 7 years Fee submitted: Rs. 5,000/-	Measure patient's eye information on sphere power, cylinder power, axis, vertex distance and pupil distance in a sequence by non contactive method through communication with patient	**Approved**.
9.	M/s Martin Dow Marker Specialties (Private) Limited. D-7, Parveen	**Manufacturer:** Boule Medical AB, Domnarvasgatan 4, SE-163 53 Spanga, Sweden.	Boule MPA Micropipettes Plastic Class A Codes: Boule MPA	The micropipettes is intended for blood collection from a finger stick or	**Approved.**

	Building, Shaheed-e-Millat Road Karachi, Pakistan. (ELI-00160) **Evaluator:** Ms. Unum Zia Shamsi	(FSC Sweden Valid till 25-05-2022)	Micropipettes Plastic, EDTA, 1x100 pcs, Ref:1070039 Boule MPA Micro Pipettes Plastic, EDTA, 10x100 pcs Ref: 1070030 Shelf Life: 36 Months Fee submitted: Rs. 5,000/-	venous sample and direct inserted into the MPA/MCI inlet of medonic CA620/530/Medonic M-Series and Swelab Alfa automated, hematology analyzers	
10.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid 25-05-2022)	Swelab Alfa Plus Standard Class A Code: 1420042 Life expectancy: 8 Years Fee submitted: Rs 5,000	Fully automatic, 3-part differential, hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.	**Approved.**
11.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Boule Medical AB, Domnarvasgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid till 25-05-2022)	Boule Cleaning Kit Class A Code: 1504111 Shelf Life: 24 Months Fee submitted: Rs 5000	Combination pack used for maintenance and cleaning of Medonic CA620/530, Medonic M-series, Swelab AC 920/970, Swelab Alfa series and Exigo automated hematology analyzers	**Approved.**
12.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Boule Medical AB, Domnarvasgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid till 25-05-2022)	Boule Enzymatic Cleaner 100mL Class A Code: 1504112 Shelf Life: 24 Months Fee submitted: Rs 5000	Intended for use with Medonic CA620/530, Medonic M-series, Swelab AC 920/970, Swelab Alfa series and Exigo automated hematology analyzers for corrective and preventive cleaning of inlets and tubing in contact with blood (protein)	**Approved.**
13.	-do-	**Manufacturer:** Boule Medical AB,	Boule Hypochlorite	Intended for	**Approved.**

	Evaluator: Ms. Unum Zia Shamsi	Domnarvasgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid till 25-05-2022)	2.0% Cleaner Class A Code: 1504113 Shelf Life: 24 Months Fee submitted: Rs 5000	use with the Medonic CA620/530, Medonic M-series, Swelab AC 920/970, Swelab Alfa series and Exigo automated hematology analyzers for corrective and preventive cleaning of inlets and tubing in contact with blood (protein)	
14.	M/s Al Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. (ELI-00285) **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Zhejiang Kekang Medical Technology Co., Ltd SouthVillage, Hongqiao town, Yueqing City, Zhejiang China (FSC China Valid 02-04-2021)	Kohlcan Adhesive Tape Class A Sizes: 1.25cm, 2.5 cm, 5 cm, 7.5 cm, 10 cm Shelf Life: 5 Years Fee submitted: Rs. 5,000/-	Non-sterile adhesive tape	**Approved**. MDB was informed that shortcomings have been received.
15.	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Zhejiang Kekang Medical Technology Co., Ltd SouthVillage, Hongqiao town, Yueqing City, Zhejiang China (FSC China Valid 02-04-2021)	Kohlcan Zinc oxide Plaster Class A Sizes: 1.25cm, 2.5 cm, 5 cm, 7.5 cm, 10 cm Shelf Life: 5 Years Fee submitted: Rs. 5,000/-	Non-sterile zinc oxide plaster	**Approved**. MDB was informed that shortcomings have been received.
16.	M/s. Asto Life Sciences. (Pvt) Plaza No. 1, Block Orchard 1, Paragon City, Barki Road, Lahore Cantt. ELI-00103 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Becton, Dickinson and Company, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth PL6 7BP UK FSC UK issue date 31.05.2018	BD Vacutainer® CAT Plus Serum Collection tube Class: A Code: 367895 367896 Shelf Life: 15 months Fee submitted: Rs. 5,000/-	Sterile, single-use, evacuated blood collection tubes that provide a means of collecting, transporting, separating, and processing blood in a closed tube.	**Approved.**
17.	-do-	**Legal Manufacturer:**	BD Vacutainer®	Sterile, single use, evacuated blood	**Approved** subject to provision of

	Evaluator: Ms. Unum Zia Shamsi	M/s Becton Dickinson. 1 Becton Drive, Franklin Lakes, NJ 07417 USA **Manufacturer Site:** Becton, Dickinson &Co. 150 S 1st Ave. Broken Bow, NE 68822 USA FSC US FDA issued on September 10, 2021	K2 EDTA (K2E) Blood Collection Tube Class A Code-Shelf life 367841-15 months 367842-15 months 367856-16 months 367861-17 months 367863-19 months 367899- 19 months Fee submitted: Rs. 5,000/-	collection tubes intended to be used for the primary containment and preservation of specimens for the purposes of measurement of many different analytes in the clinical laboratory such as hematology and immunohematology including blood donor screening. Used to obtain a whole blood or EDTA plasma sample.	Stability studies.
18.	M/s. A.H Distributors, House No. CB-708, Lane No. 5, 1st Floor, Peshawar Road, Rawalpindi. ELI-00225 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1st Road, Baolong Industrial Zone, Long gang District, 518116 Shenzhen, Guangdong, China. FSC U.K MHRA issued on 20-04-2017	Shunmei® TR-Closure Band (Air type) Class A Codes: 629904 629905 629906 629907 Shelf Life: 03 years Fee submitted: Rs. 25,000/-	Auxiliary equipment used for radial artery oppression hemostatis after the radial artery puncture interventional surgery.	**Approved subject to verification that the firm has received the Letter of Authorization before M/s Alliance Medical.**
19.	M/s Briogene Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany **Manufacturing Site:** M/s Qiagen Sciences LLC 19300 Germantown Road, Germantown, Maryland 20874, USA (FSC Germany Issuance Date	Digene® HC2 DNA Collection Device Class A Shelf Life: 36 Months 619234 Rs.5,000/-	The Digene HC2 DNA Collection Device is intended for the collection and transport of physician-collected cervical specimens to be tested only with the digene Hybrid Capture® 2 (HC2) HPV and CT/GC DNA Tests and self-collected vaginal specimens to be tested only with the digene HC2 High-Risk HPV	**Approved.**

	(829)	10-01-2019)		DNA Test.	
20.	M/s Medicamp International, Office # 1, First Floor , Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi. (ELI-00200) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Nurteks tekstil ve medikal sanayi dis ticaret anonin sirketi. Kosklu Cesme Mah Yeni Bagdat Cad No. 124 Gebze Kocaeli-Turkey (FSC Turkey valid till 4-12-2020)	Broche® Standard Surgical gown Class A Sizes: Medium, Large, X-Large, XX-Large Shelf Life: 5 Years Fee submitted: Rs 5,000/-	Sterile, disposable standard surgical gown intended to be used by medical personnel in the hospital wards, reception unites and also by the visitors in order to improve hospital infection control.	**Approved** subject to fresh Full QA Certificate.
21.	M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Omron Healthcare Co., Ltd. 53, Kunotsubo, Terado-cho, Muko Kyoto, 617-0002 Japan. **Manufacturing Site:** Krell Precision (Yangzhou) Co., Ltd. No. 28, Xingyang Road, Economic Development Zone Yangzhou, Jiangsu 225009 China. (FSC Netherlands valid till 21-03-2024)	Omron Body Composition Monitor (Body Composition Analyzer/Body Fat Analyzer) Class A Model: BF508 (HBF-508-E) Shelf Life: N/A Fee submitted: Rs. 5,000/-	Intended to be used for measuring the following body composition parameters and interpretation of the results: Body fat, Visceral fat and Body Mass Index (BMI)	**Approved.**
22.	M/s S. Ejazuddin & Co., Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain issued on 31-01-2019)	DG Gel Sol (2x100 ml) Ref No: 210354 Class: A Shelf Life: 18 months	Reagent for preparing red blood cell suspensions and plasma/serum dilutions used in gel techniques	**Approved** subject to provision of valid Letter of Authorization.
23.	M/s. Care and Cure International. 65-B, Satellite Town, Rahim	**Manufacturer:** M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei	**Cure™** Urine Bag Class A Size: 200ml, 2000ml	Sterile, disposable urine drainage bag	**Approved**.

	Yar Khan. ELI-00192 **Evaluator:** Ms. Unum Zia Shamsi	Road, Dinggou Industrial Park of Jiangdu District, Yangzhou City, 225235, P.R. China. FSC China valid till 8-01-2021	Shelf Life: 05 years Fee submitted: Rs. 25,000/-		
24.	M/s SBK International 23, Valley road, Street 3, Westridge 1, Rawalpindi ELI -00100 **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer: WIPAK OY, WIPAKTIE 2, FI-15560 NASTOLA, FINLAND. FSC Finland Issuance: 8th May, 2018.	**STERIKING® See-Through** Gusseted Pouches Gusseted Rolls Heat-Sealable Pouches Heat-Sealable Rolls Self-Sealable Pouches Class-A Shelf Life: 5 years Rs.5,000/-	Packing materials for sterilization application.	**Approved** subject to provision of Real time shelf life and Full Quality Assurance Certificate.
25.	-do- **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer: WIPAK OY, WIPAKTIE 2, FI-15560 NASTOLA, FINLAND. FSC Finland Issuance: 8th May, 2018.	**STERIKING® Creps Papers** Class-A Shelf Life: 5 years Rs.5,000/-	Packing materials for sterilization application.	**Approved** subject to provision of Real time shelf life and Full Quality Assurance Certificate.
26.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer**: WIPAK OY, WIPAKTIE 2, FI-15560, NASTOLA,FINALND FSC Finland Issuance: 8th May, 2018.	**STERIKING® PROWRAP** SMX-1 Blue Light SMX-2 Blue Regular SMX-2+ Green Regular SMX-3 Blue Heavy Duty SMX-4 Blue Super Duty	Packaging Material for sterilization	**Approved** subject to provision of Real time shelf life and Full Quality Assurance Certificate.

			Class A Shelf life 5 years Rs.5,000/-		
27.	M/s Tech Zone, 764 Askari 9, Zarar Shaheed Road, Cantt, Lahore, Ware House: Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040 **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Set Medikal, Sanayi V E tic.A.(Osmangazi Mah. Maresal fevzi cakmak cad. No:18 esenyurtBuyukcekmece/ Istanbul/Turkiye) FSC Turkey Issued on 4th May, 2017	**SET ®inject** (Disposable Syringes without Needle) Syringes without Needle. Class A Shelf Life: 05 years Sizes: 2ml, 5ml,10ml,50ml, 60ml. Rs.5,000/-	Syringe without needle is a non-invasive medical device intended for channel or storing liquid for the purpose of eventual infusion, administration or introduction into the body.	**The Board approved only 10 ml, 50 ml and 60 ml syringes.**

Item No.XXV.REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator:**	**1. 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 Ciudad Juarez Chihuhua Mexico	Coated Vicryl ™ Plus Antibacterial Suture. Class D Legal Manufacturer: Ethicon LLC Guaynabo, PR USA. Codes: VCP310H VCP311H VCP316H	A synthetic absorbable sterile surgical suture composed of a copolymer made from 90 % glycolide and 10 % L-lactide. Intended for use in general soft tissue approximation	**The Board only approved Legal manufacturer M/s Ethicon LLC and its corresponding manufacturing sites and codes and advised the firm to apply separately for other legal manufacturer(s) and its corresponding manufacturing**

	Ms. Unum Zia Shamsi	C.P. 32575. (FSC US FDA valid till 08-04-2021) **2. Legal Manufacturer:** Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium **Manufacturing Sites:** Johnson and Johnson Medical GmbH, Robert-Koch-Strasse 1, Norderstedt, 22851, Germany (FSC UK issued on 24-02-2016)	VCP317H VCP353H VCP358H VCP359H VCP1428T VCP495G Legal Manufacturer: Johnson and Johnson International, Belgium VCP247H VCP300H VCP3100H VCP3110H VCP320H VCP360H VCP9213H VCP310H FSC of US FDA and UK does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	and/or ligation including microsurgery for vessels than 2mm diameter	**site(s) and codes.**
2.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**1. Legal Manufacturer:** DePuy International Limited, St. Anthony's Road, Leeds LS11 8DT, United Kingdom. **Manufacturing Sites:** 1. Johnson & Johnson Medical (Suzhou) Ltd.No. 299 Chang Yang Street, Suzhou Industrial Park, Suzhou, Jiangsu, 215126, China 2. DePuy International Limited, St. Anthony's Road, Leeds LS11	Articul/EZE™ (Femoral Head) Class D Codes: Legal Manufacturer: DePuy International Limited, UK 1. Articul/EZE Femoral Head 12/14 Taper 28OD +5 (136512000) 2. Articul/EZE	Intended for use in Primary or Revision Total Hip Arthroplasty for the provision of improved hip joint mobility and reduction of joint pain	**The Board only approved Legal manufacturer M/s DePuy International Limited and its corresponding manufacturing sites and codes and advised the firm to apply separately for other legal manufacturer(s) and its corresponding manufacturing site(s) and codes.**

		8DT, United Kingdom. (FSC UK issued on 17-07-2018) **2. Legal Manufacturer:** DePuy (Ireland) Loughbeg, Ringaskiddy, Co. Cork, Ireland **Manufacturing Site:** No. 299 Chang Yang Street, Suzhou Industrial Park, Suzhou, Jiangsu, 215126, China (FSC Ireland valid till 15-11-2021)	Femoral Head 12/14 Taper 28OD +1.5 (136511000) 3. Articul/EZE Femoral Head 12/14 Taper 28OD +12 (136514000) 4. Articul/EZE Femoral Head 12/14 Taper 32OD +1 (136521000) 5. Articul/EZE Femoral Head 12/14 Taper 32OD +5 (136522000) 6. Articul/EZE Femoral Head 12/14 Taper 32OD +9 (136523000) Legal Manufacturer: DePuy Ireland 1. ARTICUL/ EZE BALL 32MM +1 GR 2. ARTICUL/ EZE BALL 32MM +5 BR 3. ARTICUL/ EZE BALL 32MM +9 BL 4. ARTICUL/ EZE BALL 28MM +1.5 GR 5. ARTICUL/ EZE BALL 28MM +8.5		

			BL 6. ARTICUL/ EZE BALL 28 MM+5 BR 7. ARTICUL/ EZE BALL 28MM +12 BLK Shelf life: 5 Years Fee submitted: Rs, 50,000/-		
3.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Depuy Orthopaedics. Inc. 700 Orthopaedic Dr. Warsaw, IN USA 46582 **Manufacturing sites:** 1. DePuy (Ireland) Loughbeg, Ringaskiddy, Co. Cork, Munster, Ireland 2. JOHNSON & JOHNSON MEDICAL (DEPUY-SUZHOU) LTD. No. 299, Changyang Street, Suzhou Industrial Park, Suzhou 3. CREAMTEC GmbH Medical Products Division. CreamTec- Weg 1 MARKTREDWITZ, Bayern GERMANY D-95615 4. GREATBATCH MEDICAL 4545 Kroemer Rd, Fort Wayne, IN USA	Pinnacle® Hip System Class D Codes: 121720044PINNACLE BANTAM ACET CUP 44MM 10 years 121720046PINNACLE BANTAM ACET CUP 46MM 10 years 121720048PINNACLE MULTIHOLE II CUP 48MM 10 years 121720050PINNACLE MULTIHOLE II CUP 50MM 10 years 121720052 PINNACLE MULTIHOLE II CUP 52MM 10 years 121720054 PINNACLE MULTIHOLE II CUP 54MM 10 years 121720056 PINNACLE	Total Hip prosthesis	**Approved.**

		46818 5. Haven Manufacturing. 6935 N State Road 1 OSSIAN, IN USA 46777 6. NG Instruments. 4643 N State Road 15, Warsaw, IN USA 46582 7. DEPUY ORTHOPAEDICS, INC. 325 PARAMOUNT DR. RAYNHAM, MA USA, 02767 8. NORWOOD MEDICAL 2122 Winners Circle, Dayton, OH USA 45404 9. PARAGON MEDICAL, INC. 8 Matchett Dr. PIERCETON, IN USA 46562 10. SYMMETRY MEDICAL MANUFACTURING INC. 486 west 350 North WARSAW, IN USA 46582 11. PERRYMAN COMPANY. 149 S Johnson Rd Houston, PA USA 15342 12. COORSTEK MEDICAL LLC DAYTON MFG. 811 Northwoods	MULTIHOLE II CUP 56MM 10 years 121720058 PINNACLE MULTIHOLE II CUP 58MM 10 years 121720060 PINNACLE MULTIHOLE II CUP 60MM 10 years 121720500 PINN CAN BONE SCREW 6.5MMX20MM 10 years 121722048 PINNACLE SECTOR II CUP 48MM 10 years 121722050 PINNACLE SECTOR II CUP 50MM 10 years 121722052 PINNACLE SECTOR II CUP 52MM 10 years 121722054 PINNACLE SECTOR II CUP 54MM 10 years 121722056 PINNACLE SECTOR II CUP 56MM 10 years 121722058 PINNACLE SECTOR II CUP 58MM 10 years 121722060		

		Blvd Vandalia, OH USA 45377 (FSC US FDA valid till 21-05-2021)	PINNACLE SECTOR II CUP 60MM 10 years 121725500 PINN CAN BONE SCREW 6.5MMX25MM 10 years 121730500 PINN CAN BONE SCREW 6.5MMX30MM 10 years 121735500 PINN CAN BONE SCREW 6.5MMX35MM 10 years 121740500 PINN CAN BONE SCREW 6.5MMX40MM 10 years 121745500 PINN CAN BONE SCREW 6.5MMX45MM 10 years 121828748 PINN LNR CON +4 10D 28IDX48OD 5 years 121828750 PINN LNR CON +4 10D 28IDX50OD 5 years 121832752 PINN LNR CON +4 10D 32IDX52OD 5 years 121832754 PINN LNR CON +4		

			10D 32IDX54OD 5 years 121832756 PINN LNR CON +4 10D 32IDX56OD 5 years 121832758 PINN LNR CON +4 10D 32IDX58OD 5 years 121832760 PINN LNR CON +4 10D 32IDX60OD 5 years 121836756 PINN LNR CON +4 10D 36IDX56OD 5 years 121836758 PINN LNR CON +4 10D 36IDX58OD 5 years 121836760 PINN LNR CON +4 10D 36IDX60OD 5 years 121881752 PINN DELTA CER INSRT 52ODX36ID 5 years 121881754 PINN DELTA CER INSRT 54ODX36ID 5 years 121881756 PINN DELTA CER INSRT 56ODX36ID 5 years 121881758 PINN		

			DELTA CER INSRT 58ODX36ID 5 years 121881760 PINN DELTA CER INSRT 60ODX36ID 5 years 121882748 DELTA CER INSERT 32ID X 48OD 5 years 121882750 DELTA CER INSERT 32ID X 50OD 5 years 121882752 PINN DELTA CER INSRT 52ODX32ID 5 years 121883744 PINN DELTA CER INSRT 44ODX28ID 5 years 121883746 PINN DELTA CER INSRT 46ODX28ID 5 years 121883748 PINN DELTA CER INSRT 48ODX28ID 5 years 121883750 PINN DELTA CER INSRT 50ODX28ID 5 years 121883752 PINN		

			DELTA CER INSRT 52ODX28ID 5 years 121883754 PINN DELTA CER INSRT 54ODX28ID 5 years 121883756 PINN DELTA CER INSRT 56ODX28ID 5 years 121883758 PINN DELTA CER INSRT 58ODX28ID 5 years 121883760 PINN DELTA CER INSRT 60ODX28ID 5 years 121928144 PINN MAR +4 10D 28IDX44OD 5 years 121928146 PINN MAR +4 10D 28IDX46OD 5 years 121928148 PINN MAR +4 10D 28IDX48OD 5 years 121928150 PINN MAR +4 10D 28IDX50OD 5 years 121928152 PINN MAR +4 10D 28IDX52OD 5		

			years 121928154 PINN MAR +4 10D 28IDX54OD 5 years 121928156 PINN MAR +4 10D 28IDX56OD 5 years 121928158 PINN MAR +4 10D 28IDX58OD 5 years 121928160 PINN MAR +4 10D 28IDX60OD 5 years 121932148 PINN MAR +4 10D 32IDX48OD 5 years 121932150 PINN MAR +4 10D 32IDX50OD 5 years 121932152 PINN MAR +4 10D 32IDX52OD 5 years 121932154 PINN MAR +4 10D 32IDX54OD 5 years 121932156 PINN MAR +4 10D 32IDX56OD 5 years 121932158 PINN MAR +4 10D 32IDX58OD 5 years 121932160		

			PINN MAR +4 10D 32IDX60OD 5 years 121936152 PINN MAR +4 10D 36IDX52OD 5 years 121936154 PINN MAR +4 10D 36IDX54OD 5 years 121936156 PINN MAR +4 10D 36IDX56OD 5 years 121936158 PINN MAR +4 10D 36IDX58OD 5 years 121936160 PINN MAR +4 10D 36IDX60OD 5 years 125725000 Peripheral Screws 25 mm (3 each) 10 years 136528310 ARTIC DELTA CERAMIC 28MM +1.5 5 years 136528320 ARTIC DELTA CERAMIC 28MM +5.0 5 years 136528330 ARTIC DELTA CERAMIC 28MM +8.5 5 years 136529000		

			ARTICUL/EZE BALL 22.225+4 NK 5 years 136530000 ARTICUL/EZE BALL 22.225+7 NK 5 years 136532310 ARTIC DELTA CERAMIC 12/14 32MM +1 5 years 136532320 ARTIC DELTA CERAMIC 12/14 32MM +5 5 years 136532330 ARTIC DELTA CERAMIC 12/14 32MM +9 5 years 136536310 ARTIC DELTA CERAMIC 36MM +1.5 5 years 136536320 ARTIC DELTA CERAMIC 36MM +5.0 5 years 136536330 ARTIC DELTA CERAMIC 36MM +8.5 5 years 136536340 ARTIC DELTA CERAMIC 36MM +12.0 5 years		

			Fee submitted: Rs 50,000/-		
4.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC US FDA valid 21-02-2021)	Webster fixed diagnostic catheter (4F,5F, 6F Electrophysiology catheter) Class D Codes: 37S94R 37S95R 37C53R 37C03R 37U00R 37G68R 37G58R 37D00R 37D08R 37D03R 37D05R 37D38R 37D33R 37D35R 37D58R 37D53R 37D55R 37T03R Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Indicated for electrophysiological mapping of cardiac structures i.e stimulation and recording only	**Approved.**
5.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC US FDA valid 21-02-2021)	Webster® Duo-Decapolar Electrophysiology Catheter (Deflectable Tip Electrode Catheter) Class D Code: D728260RT Shelf life: 36 months Fee submitted: Rs. 50,000/-	Indicated for electrophysiological mapping of the cardiac structures i.e stimulation and recording only. Also designed to facilitate electrogram mapping in the atrial region of the heart and coronary sinus	**Approved.**

6.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC US FDA valid 21-02-2021)	DecaNav™ Electrophysiology Catheter Class D Codes: R7D282CT R7F282CT Shelf Life: 1 year Fee submitted: Rs. 50,000/-	Indicated for electrophysiological mapping of cardiac structure i.e, recording and stimulation, including in the coronary sinus. Also used with compatible Carto® 3 EP navigation systems to provide catheter tip location information.	**Approved.**
7.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. **Manufacturing site:** Venusa de Mexico S. de. R.L de C.V Calle Hertz 1525 Parque Industrial J. Bermudez Ciudad Juarez Chihuahua Mexico 32470 (FSC US FDA valid till 13-01-2021)	SmartAblate™ Irrigation Tubing Set Class B Code: SAT001 Shelf Life: 1 Year Fee submitted: Rs. 25,000/-	Designed for use with the SMARTABLATE™ Irrigation Pump to deliver irrigation solution at specified flow rates to CELSIUS® THERMOCOOL® Catheter, NAVISTAR® THERMOCOOL® Catheter, or other irrigated devices for cooling purposes.	**Approved.**
8.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA	ThemoCool® SmartTouch™ Catheter Class D Codes: D132701 D132702 D132703 D132704 D132705	Indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction	**Approved.**

		USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC US FDA valid 21-02-2021)	D133601 D133602 D133603 Shelf Life: 1 Year Fee submitted: Rs. 50,000/-	with a radiofrequency generator, for cardiac ablation.	
9.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618 **Manufacturing site:** Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. (FSC US FDA valid till 7-3-2021)	CARTO 3 System Class B CODE: FG540000U Shelf Life: N/A Fee submitted: Rs. 25,000/-	Intended for catheter-based cardiac electrophysiological procedures. It provides information about the electrical activity of the heart and about catheter location during the procedure	**Approved.**
10.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA, 92618. **Manufacturing sites:** 1. Biosense Webster, Inc,15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC US FDA valid 21-02-2021)	ThermoCool® SF NAV Catheter Class D Codes: BNI35BBCT BNI35BBH BNI35BDCT BNI35BDH BNI35BFCT BNI35BFH BNI35DDCT BNI35DDH BNI35DFH BNI35DJH BNI35DJCT BNI35FFCT BNI35FFH BNI35FJH BNI35JJCT BNI35JJH D131501 D131502	Indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.	**Approved.**

			D131801 D131802 D131803 D131804 Shelf Life: 3 years Fee submitted: Rs. 50,000/-		
11.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**1. 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 Ciudad Juarez Chihuhua Mexico C.P. 32575. (FSC US FDA valid till 08-04-2021) **2. Legal Manufacturer:** Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issued on 20-06-2019)	Monocryl ™ Poliglecaprone 25 Suture Class D Codes: Legal Manufacturer: Ethicon LLC, Guaynabo, PR USA. W3204 W3205 W3206 W3650 W3758 W3759 Y493G Legal Manufacturer: Johnson and Johnson International, Belgium W3204 W3205 W3206 W3650 W3758 W3759 FSC of US FDA and Belgium does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 60 Months Fee submitted: Rs. 50,000/-	Sterile, synthetic monofilament absorbable sutures prepared from a copolymer of glycolide and epsilon-caprolactone. Indicated for use in general soft tissue approximation and or ligation where an absorbable material is indicated.	**The Board only approved Legal manufacturer M/s Ethicon LLC and its corresponding manufacturing sites and codes and advised the firm to apply separately for other legal manufacturer(s) and its corresponding manufacturing site(s) and codes.**

12.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969 **Manufacturing Site:** Ethicon LLC, Highway 183 Km. 8.3 San Lorenzo. PR USA 00754 (FSC US FDA valid till 18-06-2020)	Stratafix™ Symmetric PDS™ Plus Knotless Tissue Control Device Class D Codes: SXPP1A100 SXPP1A101 SXPP1A200 SXPP1A201 SXPP1A300 SXPP1A301 SXPP1A302 SXPP1A400 SXPP1A401 SXPP1A402 SXPP1A403 SXPP1A404 SXPP1A405 SXPP1A406 SXPP1A407 SXPP1A408 SXPP1A409 SXPP1A410 SXPP1A203 SXPP1A205 SXPP1A304 SXPP1A306 SXPP1A419 SXPP1A420 SXPP1A435 SXPP1A436 SXPP1A443 SXPP1A444 SXPP1A445 SXPP1A202 SXPP1A204 SXPP1A303 SXPP1A305 SXPP1A412 SXPP1A418 SXPP1A425 SXPP1A426 SXPP1A433 SXPP1A434 SXPP1A440 SXPP1A441 SXPP1A442 SXPP1A446 SXPP1A447 SXPP1A414	An anti-bacterial (polydioxenone) non filament synthetic absorbable device prepared from polyester, poly(p-dioxanone). Indicated for general soft tissue approximation where use of an absorbable suture is appropriate	**Approved.**

			SXPP1A415 SXPP1A416 SXPP1A417 SXPP1A421 SXPP1A422 SXPP1A423 SXPP1A424 SXPP1A430 SXPP1A431 SXPP1A432 SXPP1A439 SXPP1A411 SXPP1A413 SXPP1A427 SXPP1A428 SXPP1A429 SXPP1A437 SXPP1A438 FSC of US FDA does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 24 Months Fees submitted: Rs. 50,000/-		
13.	-do- **Evaluator:** Ms. Unum Zia Shamsi	1. Legal Manufacturer: Ethicon, LLC. 475 C Street, Los Frailes Industrial Park, Suite 401 Guaynabo, Puerto Rico 00969, USA Manufacturing Site: Ethicon, INC. Calle Durango No. 2751 LOTE BRAVO CIUDAD JUAREZ Chihuahua MEXICO C.P. 32575 (FSC USFDA valid till 08-04-2021) 2. Legal Manufacturer: Ethicon, LLC Highway 183 km 8.3,	Ethibond Excel™ polyester suture Class D Codes: Legal Manufacturer: Ethicon LLC, Guaynabo, PR USA. X893G X4843G X4B37G X4B77G X6977M X582H X905G X884G X894G X6757G X6761G X31059H	Sterile, braided, polybutylate coated polyester synthetic non absorbable surgical suture. Indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgicalprocedures.	**The Board only approved Legal manufacturer M/s Ethicon LLC and its corresponding manufacturing sites and codes and advised the firm to apply separately for other legal manufacturer(s) and its corresponding manufacturing site(s) and codes.**

		San Lorenzo, Puerto Rico 00754, USA Manufacturing Site: Ethicon, LLC Highway 183 km 8.3, San Lorenzo, Puerto Rico 00754, USA (FSC USFDA valid till 03-04-2021)	X32071H X31083H W6191 W10B52 W10B54 W10B55 W10B72 W10B77 W4843 W4846 W6552 W6767 W6935 W6936 W6937 W6977 W893 X523H X937H 10X42N 10X82N PXX41N PXX43N PXX76N PXX80N 10X86N Legal Manufacturer: Ethicon LLC, San Lorenzo, Puerto Rico. USA. W6582G W979G X518H X517H W975G W6832 W4846 W6937 W6977 W893 X523H W4846G FSC of US FDA does not have codes. The manufacturer has given list of codes (notarized) that		

			are manufactured by them. Shelf Life: 60 Months Fee submitted: Rs. 50,000/-		
14.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 **Manufacturing Site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 08-04-2021)	Surgical Stainless Steel Suture Class C Codes: M650G M651G MF665 M400G Shelf Life: 60 Months Fee submitted: Rs. 50,000/-	Sterile, surgical non absorbable stainless steel suture for use in abdominal wound closure, hernia repair, sternal closure and othopaedic procedures including cerclage and tendon repair.	**Approved.**
15.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**1. 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 Ciudad Juarez Chihuhua Mexico C.P. 32575. (FSC US FDA valid till 08-04-2021) **2. Legal Manufacturer:** Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issued on 02-07-2019)	Vicryl™ (Polyglactin 910) Suture Class D Codes: Legal Manufacturer: Ethicon LLC, Guaynabo, PR USA. J434H J442H J544G W9105 W9221 W9391 W9442 W9443 W9444 W9506T W9510T W9511T W9521T W9522T W9552 W9560 W9561 W9565	Sterile synthetic absorbable surgical suture composed of co-polymer made from 90% glycolide and 10% L-lactide. Intended for use in general soft tissue approximation and / or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2mm diameter.	**The Board only approved Legal manufacturer M/s Ethicon LLC and its corresponding manufacturing sites and codes and advised the firm to apply separately for other legal manufacturer(s) and its corresponding manufacturing site(s) and codes.**

			W9567 W9580T W9581T W9582T W9718 W9719 W9828 Legal Manufacturer: Johnson and Johnson International, Belgium W9023 W9024 W9025 W9106 W9130 W9350 W9377 W9378 W9890 W9375 W9500T W9514T W9531T W9566 W9575 W9831T W9832T FSC of US FDA and Belgium does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 60 Months Fee submitted: Rs. 50,000/-		
16.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W.,	Ramp® Procalcitonin Controls Class C	Intended for invitro diagnostic use in the quality	**Approved.**

	Court, Main Clifton Road, Karachi (ELI-00030) **Evaluator:** Ms. Unum Zia Shamsi	Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	Shelf Life: 24 Months Ramp® Procalcitonin Controls Level 1 Ref: C3003-1 Ramp® Procalcitonin Controls Level 2 Ref: C3003-2 Fee submitted: Rs. 50,000/-	control of the accuracy of the RAMP calcitonin assay	
17.	M/s Aftab Life Care Impex, 1st Floor Al-Falah Chambers, Tilak Road Hyderabad. (ELI-00357) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** EPS Bio Technology Corp. No. 8 R&D Rd III, Hsinchu Science Park, Hsinchu County, Taiwan, ROC 30077. (FSC issued by Ministry of Health and Welfare, Republic of China (Taiwan) on 18-07-2017 attested by Jordanian commercial office-Taipei)	EASYMAX® Mini Self-Monitoring Blood Glucose System. Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for the quantitative measurements of glucose in fresh capillary whole blood and venous blood from fingertip, palm and forearm.	**Approved** subject to of manufacturer abroad or CE marked documents. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
18.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1102]	**Legal Manufacturer:** EPS Bio Technology Corp No. 8 R&D Rd III, HsinchuScien Park, Sinchu, T*aiwa*n 30077 ROC. (FSC **T*aiwa*n** Valid till23-09-2021)	EASYMAX® Blood Glucose Test Strip. Shelf Life: 24 Months Sizes & Codes: EasyMax Blood Glucose Test Strips :25 pcs, 50 pcs (25 pcs x 2) Rs.50,000/- Class C	The strips are intended for the quantitative measurement of glucose in fresh venous blood and capillary whole blood sample using EASYMAX® blood glucose monitoring System.	**Approved** subject to foreign inspection of manufacturer abroad or CE marked documents and provision of Embassy attested **FSC , Real time stability data supporting claimed shelf life of 2 years and Last audit report.** The Board also authorized the Secretary MDB to issue registration of the product, if

					the panel of experts approves the manufacturing plant.
19.	M/s. Surgi World Office No. 303, Muhammadia Plaza, College Road, Rawalpindi. (ELI-00212) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** BARD PERIPHERAL VASCULAR, INC. 1625 W 3RD St, TEMPE, AZ, USA 85281 **Manufacturer Site:** M/S FOREFRONT MEDICAL TECHNOLOGY (JIANGSU) CO, LTD. No. 8, Chang Yang Road, Wujin Economic Zone, Changzhou, Jiangsu, China 213 145 FSC US FDA valid till December, 14, 2019	PRESTO™ Inflation Device Class B Ref No: ID4030 Shelf Life: 03 years Fee submitted: Rs.25,000/-	Indicated for use with angioplasty balloon dilatation catheter to create and monitor the pressure in the angioplasty balloon dilatation catheter and to deflate the angioplasty balloon dilatation catheter	**Approved** subject to provision of valid Free Sale Certificate duly attested by Embassy of Pakistan.
20.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625W 3rd st Tempe, AZ USA 85281 **Manufacturing Site:** Bard Shannon Limited San Geronimo Industrial Park Lot No.1 Road No. 3, Km 79.7 Humacao, PR USA 00791. FSC USA Validity 13-02-2021	**Bard® Javid™ Carotid Bypass Shunt** Code: 007714 Class D Shelf Life: 3 Years Rs.50,000/-	They are indicated to be a temporary blood conduit in the carotid arteries during a carotid endarterectomy procedure.	**Approved** subject to provision of updated LOA and Confirmation of shelf life claim.
21.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Bard Access System, Inc. 605 North 5600 West Salt Lake City, UT USA. **Manufacturing Site:** C.R BARD , INC 289, Bay Rd, Queensbury, (NY) USA	**NAVARRE ® DRAINAGE CATHETER** NOD 8PT NOD 8LPT NOD 10PT NOD 10LPT NOD 12PT NOD 12LPT Class B	Intended to be used for abscess, cyst and other general purpose drainage applications.	**Approved** subject to provision of updated LOA, ISO for manufacruing site and Shelf-life supported by studies.

		FSC USA Valid till, September, 05,2020	Shelf Life 3 years Rs.50,000/-		
22.		**Legal Manufacturer:** Angiomed GmbH & Co. Medizintechnik KG, Wachausstrasse 6, 76227 Karlsruhe, Germany FSC Germany Issue date 22.01.2019	**Angiomed PTFE COATED GUIDE WIRE** 02200020 02200030 02200040 02200050 02200080 02220020 02220040 02220050 02250040 02250050 02250060 02250080 02270050 02290020 02290040 02290050 02310020 02310030 02310040 02310050 02310057 02310060 02310070 02310080 02310090 02310100 02310110 02330030 02330040 02330050 02330060 02330070 02330080 03000050 03000060 03020050 03020060 03040050 03060050 03060060 03070040 03070050 03100060 03300040	A guide wire, for interventional procedures.	**Approved** subject to provision of MRP, Valid ISO and Real time Shelf life studies.

			03300050 03350030 03350040 03350050 03370050 03390040 03390050 03410020 03410030 03410040 03410050 03410051 03410055 03410060 03410070 03410080 03430020 03430030 03430040 03430050 03430080 03670050 Class D Shelf Life 3 years		
23.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Angiomed GmbH & Co. Medizintechnik KG, Wachausstrasse 6, 76227 Karlsruhe, Germany FSC Germany Issue date 22.01.2019	**Angiomed PERCUTANEOUS KIDNEY DRAINAGE** 55000010 55000030 55000040 55000050 55000070 55000080 55000090 Class C Shelf Life 3 years Rs.50,000/-	A catherization method use to drain the kidneys, when an obstruction has blocked the urinary passage.	**Approved** subject to provision of Valid ISO.
24.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Bard Access System, Inc. 605 North 5600 West Salt Lake City, UT USA. **Manufacturing Sites:**	**X- PORT™ isp Implantable port** **0607500, 0607510, 0607520, 0607525, 0607530,**	The X- port isp ™ Implantable ports are indicated for patient therapies requiring repeated access	**Approved** subject to provision of valid Design Examination Certificate and updated LOA

		Bard Reynosa S.A. DE C.V. BLVD. MONTBELLO No. 1, PARQUE INDUSTRIAL COLONIAL REYNOSA, Tamaulipas, Mexico FSC USA (FDA) Valid till July, 02, 2020	**0607540, 0607550, 0607555, 0607560, 0657500, 0657510, 0657520, 0657525, 7707540, 7757540** Class D Shelf Life 5 years Rs.50,000/-	to the vascular system. The port system can be used for infusion of medications, I.V.fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.	
25.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Bard Access Systems Inc. 605 North 5600 West Salt Lake City Ut, USA 84116 **Manufacturing Sites:** Bard Reynosa S.A. DE C.V. BLVD. MONTBELLO No. 1, PARQUE INDUSTRIAL COLONIAL REYNOSA, Tamaulipas, Mexico FSC USA Valid till Feb.13, 2021	**GROSHOGN ® 9.5F DUAL LUMEN CENTRAL VENOUS CATHETER** **7724950** **7726950** Class D Shelf Life 5 years Rs.50,000/-	The Groshong 9.5F Dual Lumen Catherters are designed for long term vascular access and for use in patients that lack adequate peripheral venous access.	**Approved** subject to provision of Executive summary of shelf life
26.	-do- **Evaluator:** Shahid Muhammad Iqbal	Legal Manugacturer: Davol, Inc, SUBSIDIARY OF C.R Bard,.INC. 100 Crossing Blvd. Warwick, Rhode Island USA. Manufacturing Site: Bard Shannon Ltd San Geronomo Industrial park Lot # I Road # 3, km 79.7 Humacao, Puerto rico (00791 USA. FSC USA valid till 5th	**Bard® 3D Max™ Light Mesh** 0117310 0117311 0117312 0117320 0117321 0117322 Class-C Shelf Life: 5 years Rs.50,000/-	The 3DMax ™ light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the reapir of inguinal hernias.	**Approved** subject to provision of MRP, LOA and ISO for manufacturing site.

		September,2020			
27.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Bard Access System, Inc.605 North 5600 WestSalt Lake City, UT USA. **Manufacturing 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 FSC USA (FDA) Valid till July, Feb.13, 2021	**BROVIAC ® Central Venous Catheter** **0600520** **0600540** **0600040** Class D Shelf Life 5 years Rs.50,000/-	BROVIAC® CENTRAL VENOUS CATHETERS are designed for long-term vascular access and for use in patients that lack adequate peripheral venous access.	**Approved** subject to provision of updated LOA.
28.	-do- **Evaluator:** Shahid Muhammad Iqbal	**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	**Approved** subject to provision of updated LOA.

				parenteral.	
29.	M/s Medequips SMC (Pvt) Ltd. 30-Shahrah-e-Quaid-e-Azam, Lahore. (ELI-00362) **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Imaxeon Pty Ltd Unit 1 /38-46 South Street Rydalmere, NSW, 2116 Australia. (FSC TGA Australia issued on 17-10-2018)	Salient Syringe 190 ml Class B Shelf Life: 5 Years Ref No: ZY6322 190 ml Syringe with QFT ZY6323 190 ml Syringe with Spike ZY6324 190 ml Syringe, Spike, 150 cm connecting tube ZY6325 190 ml Syringe, QFT, 150 cm connecting tube Fee submitted: Rs. 25,000/-	Used for the purpose of venous injection of contrast media and common flushing solutions into adult and pediatric patients during x-ray proceudure, together with Imaxeon Salient Contrast Injection Systems. Single-use, sterile.	**Approved.**
30.	M/s. Care and Cure International.65-B Satellite Town Rahim Yar Khan. (ELI-00192) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei Road, Dinggou Industrial Park of Jiangdu District, Yangzhou City, 225235, P.R. China. FSC China valid till 8-01-2021	**Cure™** Disposable Infusion Set Class B Codes: IS-VB1, IS-VB2, IS-VB3, IS-VB4, IS-VE1, IS-VE2 Shelf Life: 05 years Fee submitted: Rs. 25,000/-	Sterile, single use infusion set	**Approved** subject to provision of product brochure to differentiate among different codesand foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approves the manufacturing plant.
31.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei Road, Dinggou Industrial	**Cure™ Burette Infusion Set** Class B Size: 100ml Shelf Life: 05 years	Sterile, single-use burette infusion set	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the

		Park of Jiangdu District, Yangzhou City, 225235, P.R. China. FSC China valid till 8-01-2021	Fee submitted: Rs. 25,000/-		Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approve the manufacturing plant.
32.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei Road, Dinggou Industrial Park of Jiangdu District, Yangzhou City, 225235, P.R. China. FSC China valid till 8-01-2021	Cure™ Auto Disable Syringe Class B Sizes: 0.5ml, 1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml Shelf Life: 05 years Fee submitted: Rs. 25,000/-	Sterile, single-use Auto Disable Syringe with needle.	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approve the manufacturing plant.
33.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei Road, Dinggou Industrial Park of Jiangdu District, Yangzhou City, 225235, P.R. China. FSC China valid till 8-01-2021	**Cure™**Umbilical cord clamp Class B Size: 5cm, 5.5cm, 5.8cm, 6cm Shelf Life: 05 years Fee submitted: Rs. 25,000/-	Sterile, single-use device intended for clamping umbilical cord when women give birth to a baby.	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approves the manufacturing plant.
34.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AnHui AnYu Latex Products Co., Ltd., No. 95, YuHe Road, 233010,	Cure™Sterile Latex Surgical Gloves (powder-free) Class B	Powder free, sterile, single-use, latex surgical gloves	**Approved** subject to foreign inspection of manufacturer

		Bengbu, AnHui, China. FSC China valid till 19.12.2020	Size: 6, 6.5, 7, 7.5, 8, 8.5 (2 pcs or 1 pair per pack) Shelf Life: 03 years Fee submitted: Rs. 25,000/-		abroad. The Board also authorized the Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approves the manufacturing plant.
35.	M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi (ELI-00007) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s Nipro Corporation, 3-9-3 Honjo-Nishi, Kita-Ku, Osaka 531-8510, Japan **Manufacturing site:** M/s Nipro Medical Industries Ltd. Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan (FSC Japan issued on 04-03-2019)	Nipro Spinal Needle Class D Sizes 18G, 20G,21G, 22G, 23G, 25G, 26G, 27G Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	A punching needle used for administration of anaesthetics into spinal subarachnoid space and for collection of cerebrospinal fluid	**Approved.**
36.	M/s. Physiomed (Pvt) Ltd, 268/3, Kamal Road, Saddar Rawalpindi. (ELI-00199) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer** M/s. St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342 USA **Manufacturing sites:** 1. M/s. St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342 USA 2. M/s. St. Jude Medical Puerto Rico LLC, Lot A Interior #2 Rd km.67.5, Santana Industrial Park, Arecibo PR 00612, USA	Quadra Allure MP™ (MR Conditional) Model PM3562 Class D Shelf Life: 18 months Fee submitted: Rs. 50,000/-	Cardiac resynchronization therapy Pacemaker (CRT-P). An active implantable medical device indicated to provide pacing and sensing to resynchronize the right and left ventricles in patients with congestive heart failure	**Approved** subject to provision of valid Design Examination certificate.

		3) M/s. St. Jude Medical Operations (M) Sdn. Bhd Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, Malaysia. **FSC Belgium issued on 23-10-2018**			
37.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Plot No. 3, MCHS Society, Shaheed-e-Millat Road, Karachi (ELI-00274) **<u>Evaluator</u>:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s AESKU. Diagnostics GmbH & Co. KG Mikroforum Ring 2, D-55234, Wendelsheim, Germany (FSC Germany Issue Date 27-04-2018)	AESKUSLIDES 1. AESKUSLIDES ANA -HEp-2 Kit 120 tests Ref: 51.100 Shelf life: 2 years 2. AESKUSLIDES ANA-HEp-2 Kit 600 tests Ref: 51.100.Bulk5 Shelf life: 2 years 3. AESKUSLIDES ANA-HEp-2 Kit 120 tests Ref: 51.101 Shelf life: 2 years 4. AESKUSLIDES ANA-HEp-2 Kit 600 tests Ref: 51.101. Bulk5 Shelf life: 2 years 5. AESKUSLIDES EMA IgA Kit 50 tests Ref: 512.050 Shelf life: 18 months 6. AESKUSLIDES EMA IgG	Indirect immuno fluorescence assays to detect autoantibodies in human serum	**Deferred.** IVD cluster Need guidance

			Kit 50 tests Ref: 512.060 Shelf life: 18 months 7. AESKUSLIDES EMA IgA Kit 100 tests Ref: 512.100 Shelf life: 18 months 8. AESKUSLIDES EMA IgG Kit 100 tests Ref: 512.101 Shelf life: 18 months 9. AESKUSLIDES rLKS (wrapped) Kit 50 tests Ref: 517.050 Shelf life: 18 months 10. AESKUSLIDES rLKS (separated) Kit 50 tests Ref: 517.051 Shelf life: 18 months 11.AESKUSLIDES rLKS (separated) Kit 100 tests Ref: 517.100 Shelf life: 18 months 12. AESKUSLIDES rLKS (wrapped) Kit 100 tests Ref: 517.101 Shelf life: 18 months		

			13. AESKUSLIDES nDNA (Crith luc) Kit 100 tests Ref: 53.100 Shelf life: 24 months 14. AESKUSLIDES ANCA Ethanol (Crith luc) Kit 60 tests Ref: 54.050 Shelf Life: 24 months 15. AESKUSLIDES ANCA Formalin Kit 60 tests Ref: 54.051 Shelf life: 18 months 16. AESKUSLIDES ANCA Ethanol Kit 120 tests Ref: 54.100 Shelf Life: 24 months 17. AESKUSLIDES ANCA Formalin Kit 120 tests Ref: 54.101 Shelf life: 18 months Class B Fee submitted: Rs. 25,000/-		
38.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1092]	**Legal Manufacturer:** Dirui Industrial Co., Ltd. No. 95 YunheStr, New & High Tech Development zone, Changchun China. (FSC China Valid 17-	DIRUI H 100 Urine Analyzer (Urine Analyzer) Class B Analyzer Life: 7 Years Shelf Life: Strips 24 Months	Urine Analyzer	**Approved** subject to foreign inspection of manufacturer abroad or proviosion of CE marking

		12-2020)	Sheath 18 Months Detergents 12 Months (Sizes & Codes as Per FSC) Strips codes: ???? Rs.25,000/-		documents or evidecnce of registration of reference countries. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
39.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) [1131] **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428 USA **Contract Manufacturer:** MedplastMedical Inc.620 Watson Sw GR. MI USA 49504 (FSC US FDA valid till 03-01-2020)	URCHIN® EVO Heart Positioner (HP3500) Class B Shelf Life: 3 Years (Sizes & Codes as Per FSC)	The Urchin Evo Heart Positioner is a disposable, retractor based device that incorporates a silicone suction apparatus, an articulating arm, and a mounting clamp. Intended use: This product is intended for use during coronary artery bypass grafting operations. The intended function of this product is for positioning the heart.	**Approved subject to submission of differential fee Rs. 25000/- for Class D.**
40.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1132]	**Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr	Starfish® NS Heart Positioner HP102 (Patient Positioning vacuum Pad) Class B Shelf Life 3 Years	The device designed to position and immobilizes parts of the patients (e.g Head, Extremities) typically during	**Approved subject to submission of differential fee Rs. 25000/- for Class D.**

		Minneapolis, MN 55428 USA **Contract Manufacturer:** MedplastMedical Inc. 620 Watson Sw GR. MI USA 49504 (FSC US FDA valid till 03-01-2020)	**Rs.50,000/-** (Sizes & Codes as Per FSC)	therapeutic interventions or patients transportation. The device immobilizes a body part by encompassing it and then apply a vacuum The device is typically an airtight soft pillow case type of covering made of flexible materials. e.g. plastic or rubber. When sealed, this device retains the shape of the part that it encompasses until the vacuum is released.	
41.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1135]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN55428 USA **Contract Manufacturer:** MedplastMedical Inc. 620 Watson Sw GR. MI USA 49504 (FSC US FDA valid till 08-03-2020)	DLP® Femoral Arterial Cannula (Cardiopulmonary bypass cannula, arterial) Class D Shelf life 3 Years Codes&Sizes: DLP® Femoral Arterial Cannulae 57414_DLP® Femoral Arterial Cannulae 57417_DLP® Femoral Arterial Cannulae 57421_DLP® Femoral Arterial Cannulae 57517_DLP® Art Cannula, Femoral, 3/8" Non Vented	A sterile or semi-rigid tube designed to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. It is typically a 9 to 24 Fr tube with an end hole (some may include side holes): It is Short enough to keep the distal tip inside the femoral vessel. The tube is used in set ups/ systems	**Approved** subject to provision of stability study having claimed shelf life

			Connector, 17 Fr 57521_DLP® Art Cannula, Femoral, 3/8" Non Vented Connector, 21 Fr **Rs.50,000/-**	intended to divert the patients' blood to and from external tubing and an arterial pump, bypassing the heart and lungs completely. This is a single use device.	
42.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1137]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428 USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Manufacturing Facility:** Medtronic Perfusion Systems 18501 E Plaza Dr Parker, Co USA 80134. (FSC US FDA valid till 13-09-2019) EXPIRED	MyOtherm XP® 4:1B (Cardioplegia Delivery system with Bridge) Cardioplegia Solution administration Kit. Class C Shelf Life: 2 Years Rs.50,000/- (Sizes & Codes as Per FSC) 61399405331 MyOtherm XP® 4 :1B	The device is intended for the mixing, warming/ cooling and delivery of oxygenated blood/ cardioplegia Solution in a predetermined ratio.	**Approved.**
43.	-do- **Evaluator:** Hafiz Muhammad	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA	Coagulation Instrument –ACT Plus® Automated Coagulation timer	The instrument is intended for in vitro diagnostic testing in either	**Approved** subject to provision of Design Examination certificate.

	Asif Iqbal [1139]	**Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428 USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Manufacturing Facility:** Medtronic Perfusion Systems 18501 E Plaza Dr Parker, Co USA 80134. (FSC US FDA valid till 13-09-2019) expired	IVD Class D Shelf Life : N/A Codes & Sizes: ACT 100- ACT Plus®, 100-120V ACT 200- ACT Plus®, 200-240V ACT 20001- ACT Plus®, 200-240V ACT 20002- ACT Plus®, 200-240V ACT 20003- ACT Plus®, 200-240V ACT 20004- ACT Plus®, 200-240V ACT 20005- ACT Plus®, 200-240V ACT 20006- ACT Plus®, 200-240V ACT 20008- ACT Plus®, 200-240V ACT 20024- ACT Plus®, 200-240V ACT 20041- ACT Plus®, 200-240V ACT 20046- ACT Plus®, 200-240V	a hospital laboratory setting or a point of care (decentralized) setting (e.g, in the operating room, cardiac catheterization lab, intensive care unit, or clinic, etc.	
44.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1142]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428 USA **Manufacturer:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504 (FSC US FDA valid Till 08-03-2020)	Bio-Medicus® One Piece Femoral Cannulae Cardiopulmonary Bypass cannula, Femoral Class D Shelf Life: 3 Years Sizes & Codes : Bio-Medicus® One Piece Femoral Cannulae 96820-008-Bio-medicus®Art. Cannula, ¼" non-vent con., 8Fr 96820-010-Bio-medicus®Art. Cannula, ¼" non-vent con., 10Fr 96820-012-Bio-	A Sterile, rigid or semi-rigid tube designed to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. It is typically a 9 to 24 Fr tube with an end hole(Some may include side holes) it is a short enough to keep the distal tip inside the femoral vessel. The tube is used in set-ups/systems	**Approved.** **Product applied is** Bio-Medicus® One Piece Femoral(**Arterial**)Cannulae but the submitted fee is of product Bio-Medicus® One Piece Femoral **Venous** Cannulae. Discus with KHALID SAHB

			medicus®Art. Cannula, ¼" non-vent con., 12Fr 96820-014-Bio-medicus®Art. Cannula, ¼" non-vent con., 14Fr 96570-015_ Bio-medicus®Art. Cannula, Adult, 3/8" conn. w/vent, 15 Fr. 96570-017_ Bio-medicus®Art. Cannula, Adult, 3/8" conn. w/vent, 17 Fr. 96570-019_ Bio-medicus®Art. Cannula, Adult, 3/8" conn. w/vent, 19 Fr. 96570-021_ Bio-medicus®Art. Cannula, Adult, 3/8" conn. w/vent, 21 Fr. Rs.50,000/-	intended to divert the patients' blood to and from external tubing and arterial pump, bypassing the heart and lungs completely. This is a single use device.	
45.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1144]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428 USA **Manufacturer:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504 (FSC US FDA valid Till 08-03-2020)	Bio-Medicus ® One Piece Venous Femoral Cannula Cardiopulmonary bypass cannula, Femoral Class D Shelf Life: 3 Years Sizes & Codes Bio-Medicus ® One Piece Venous Femoral Cannula 96830-008_ Bio-Medicus® Venous Cannula, ¼" non-vent con., 8 Fr. 96830-010_ Bio-Medicus® Venous Cannula,	A Sterile, rigid or semi-rigid tube designed to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. It is typically a 9 to 24 Fr tube with an end hole(Some may include side holes) it is a short enough to keep the distal tip inside the femoral vessel. The tube is used in set-ups/systems	**Approved.**

			¼" non-vent con., 10 Fr. 96830-0012_ Bio-Medicus® Venous Cannula, ¼" non-vent con., 12 Fr. 96830-014_ Bio-Medicus® Venous Cannula, ¼" non-vent con., 14 Fr. 96670-015_Bio-Medicus® Venous Femoral Cannula, 3/8" non vent con., 15Fr., 96670-017_Bio-Medicus® Venous Femoral Cannula, 3/8" non vent con., 17Fr., 96670-019_Bio-Medicus® Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-021_Bio-Medicus® Venous Femoral Cannula, 3/8" non vent con., 21Fr., 96370-023_Bio-Medicus® Venous Femoral Cannula, 1/2" non vent con., 23Fr., 96370-025_Bio-Medicus® Venous Femoral Cannula, 1/2" non vent con., 25Fr., 96370-027_Bio-Medicus® Venous Femoral	intended to divert the patients blood to and from external tubing and arterial pump, bypassing the heart and lungs completely. This is a single use device.	

			Cannula, 1/2" non vent con., 27Fr., 96370-029_Bio-Medicus® Venous Femoral Cannula, 1/2" non vent con., 29Fr., Rs.50,000/-		
46.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1143]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN 55432 USA **Manufacturer:** Medtronic AFT 8200 Coral Sea Street Moundsview, MN USA 55112. **Contract Manufacturer:** Bovie Medical Corporation 5115 Ulmerton Road Clearwater, FL USA 33760. (FSC US FDA valid 07-11-2019)	Cardioblate® 68000 Surgical Ablation System Radio-frequency ablation system Class C Shelf Life: Not mentioned on the Form	The device designed to generate radio-frequency (RF) electrical current used to create heat via an electrode in precise location, at a controlled temperature, for focal ablation of non-cardiac tissues, including nerves, tumors, precancerous tissue. It may be intended for coagulation however it is not intended for electrosurgical cutting. The generator connects via a delivery cable to an electrosurgical cutting. The generator connects via a delivery cable to an electrosurgical ablation probe/ catheter (not	**Approved** subject to clarification whether the product applied is Cardioblate® 68000 Surgical Ablation System or Cardioblate **CryoFlex** Surgical Ablation System.

				included) to transmit the RF electrical current to the operative site: it may additionally be intended to heat an electrode tip.	
47.	M/s Pharma Consultant Pakistan (Pvt) Ltd., Suit NO. 207, 207 A Khan Tower, DHA Square Walton Road, Lahore. **Evaluator:** Hafiz Muhammad Asif Iqbal [43-P]	M/s. LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX USA 77058 FSC USFDA Valid till 07.11.2019	VNS Therapy Demipulse Model 103Generator (VNS Therapy System) Code/Model: Demipulse generator 103 Class D Shelf Life : 02 years (Generator) Rs.50,000/-	The system, used for vagus nerve stimulation (VNS).	**Approved subject toprovision of valid Free Sale Certificate.**
48.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [44-P]	M/s. LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX USA 77058 FSC USFDA Valid till 07.11.2019	VNS Therapy AspireSR Model 106Generator (VNS Therapy System) Cpde/Model: AspireSR generator 106 Class D Shelf Life : 02 years (Generator) Rs.50,000/-	The systemused for vagus nerve stimulation (VNS).	**Approved subject toprovision of valid Free Sale Certificate.**
49.	M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073) **Evaluator:** Hafiz Muhammad Asif Iqbal [983]	**Legal manufacturer:** Karex Industries Sdn .Bhd. Ptd. 7906 & 7907 Taman Pontian Jaya BT. 34, Jalan Johor, 82000, Pontian, Johor DarulTakzim, Malaysia. (FSC UK Issued on 30-01-2019)	Happy Life – Collection Natural Rubber Latex Male Condoms (non flavored) Class C Shelf Life5 Years Rs.50,000/-	Natural Rubber Latex Male Condoms (non flavored)	**Rejected** as the sameproduct by the manufacturer with different brand namehas already been approved in the name of M/s Krestacorp in 12th MDB meeting.

50.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [984]	**Legal manufacturer:** Karex Industries Sdn .Bhd. Ptd. 7906 & 7907 Taman Pontian Jaya BT. 34, Jalan Johor, 82000, Pontian, Johor DarulTakzim, Malaysia. (FSC UK Issued on 30-01-2019)	Happy Life – Dotted Natural Rubber Latex Male Condoms (non flavored) Class C Shelf Life 5 Years Rs.50,000/-	Natural Rubber Latex Male Condoms (non flavored)	**Rejected** as the sameproduct by the manufacturer with different brand namehas already been approved in the name of M/s Krestacorp in 12th MDB meeting.
51.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [985]	**Legal manufacturer:** Karex Industries Sdn .Bhd. Ptd. 7906 & 7907 Taman Pontian Jaya BT. 34, Jalan Johor, 82000, Pontian, Johor DarulTakzim, Malaysia. (FSC UK Issued on 30-01-2019)	Happy Life - Intense Buttercup Natural Rubber Latex Male Condoms (non flavored) Class C Shelf Life 5 Years Rs.50,000/-	Natural Rubber Latex Male Condoms (non flavored)	**Rejected** as the sameproduct by the manufacturer with different brand namehas already been approved in the name of M/s Krestacorp in 12th MDB meeting.
52.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [986]	**Legal manufacturer:** Karex Industries Sdn .Bhd. Ptd. 7906 & 7907 Taman Pontian Jaya BT. 34, Jalan Johor, 82000, Pontian, Johor DarulTakzim, Malaysia. (FSC UK Issued on 30-01-2019)	Happy Life – Regular Natural Rubber Latex Male Condoms (non flavored) Class C Shelf Life 5 Years Rs.50,000/-	Natural Rubber Latex Male Condoms (non flavored)	**Rejected** as the sameproduct by the manufacturer with different brand namehas already been approved in the name of M/s Krestacorp in 12th MDB meeting.
53.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [987]	**Legal manufacturer:** Karex Industries Sdn .Bhd. Ptd. 7906 & 7907 Taman Pontian Jaya BT. 34, Jalan Johor, 82000, Pontian, Johor DarulTakzim, Malaysia. (FSC UK Issued on 30-01-2019)	Happy Life- Rough & Tough Natural Rubber Latex Male Condoms (non flavored) Class C Shelf Life 5 Years Rs.50,000/-	Natural Rubber Latex Male Condoms (non flavored)	**Rejected** as the sameproduct by the manufacturer with different brand namehas already been approved in the name of M/s Krestacorp in 12th MDB meeting.
54.	M/s PharmEvo(Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi	**Legal Manufacturer:** OMRON Healthcare Co., Ltd. 53, Kunotsuba, Terado-cho, Muko, KYOTO, 617-0002 Japan. **Manufacturing Facilities:**	OMRON NE-C28 P(OMD) NE-C803(OHV) Compressor Nebulizer	Compressor Nebulizer	**Approved.**

	(ELI-00055) **<u>Evaluator</u>:** Hafiz Muhammad Asif Iqbal [959]	(i) OMRON Dalian Co., Ltd(OMD) No.3. Song Jiang Raod Economic & Technical Development Zone Dalian 11600, P. R. China. (ii) OMRON Healthcare Manufacturing Vietnam Co., Ltd. (OHV) 28 VSIP, Street 2, Vietnam- Singapore Industrial Park II BinhDoung Province, Vietnam. FSC Netherlands Valid till 21-03-2024	Class B Shelf Life: N/A Rs.25,000/-		
55.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Omron Healthcare Co., Ltd., 53, Kunotsubo, Terado-cho, Muko Kyoto, 617-0002 Japan. (FSC Netherland issued 16-05-2019)	Omron M7 Intelli IT (Automatic Upper blood pressure monitor) Class B Shelf Life: N/A Sizes & Codes as Per FSC HEM-7322T-E	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient.	**Approved.**
56.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Omron Healthcare Co., Ltd., 53, Kunotsubo, Terado-cho, Muko Kyoto, 617-0002 Japan. (FSC Netherland issued 16-05-2019)	Omron M3 (Automatic Upper Arm Blood Pressure Monitor) Class B Shelf Life: N/A Sizes & Codes as Per FSC HEM-7131-E	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient.	**Approved.**
57.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Omron Healthcare Co., Ltd., 53, Kunotsubo, Terado-	Omron M6 Comfort (Automatic Upper Arm Blood Pressure Monitor)	The device is a digital monitor intended for use in measuring	**Approved.**

		cho, Muko Kyoto, 617-0002 Japan. (FSC Netherland issued 16-05-2019)	Class B Shelf Life: N/A Sizes & Codes as Per FSC HEM-7321-E	blood pressure and pulse rate in adult patient.	
58.	M/s IBL HealthCare Limited, 9th Floor, NICL Building, AbbasiShaheed Road, Karachi (ELI-00119) **Evaluator:** Hafiz Muhammad Asif Iqbal [952]	**Legal Manufacturer:** ShangdongWeigao Group Medical Polymer Co., Ltd No.18 Xingshan Road, Torch Hi-tech Industry Development Zone, Weihai, China.	WEGO Blood Transfusion Set Class B Shelf Life: 2 Years Sizes: 1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml Rs.25,000/-	Blood Transfusion is used for transferring the blood from the blood bag to body.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and real time stability data.
59.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc.1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland , Unit 424/425, Contact Lens Division Industrial Estate, Cork Rd Waterford, Munster, Ireland FSC USFDA Valid Till 29-08-2020	SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lenses Pack Sizes (5s, 30s, 90s) Class B Shelf Life: 60 Months Rs.25,000/-	Single-use disposable wear in spherical powers lens.	**Approved** subject to provision of valid FQA, Readable labels, Original documents.
60.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer/ Legal Manufacturer:** M/s Bausch & Lomb Inc.1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s B.L. Industria	SofLens Soft Contact Lenses, daily wear and extended wear (Polymacon) Class B Shelf Life: 60	Soflens natural colors (daily wear or extended wear 1-7 days)	**Approved** subject to provisionvalid FQA, Readable labels.

		Otica Ltda., Rua Dona Alzira 139, Porto Alegre RS, 91110-010, Brazil FSC Ireland Valid Till 01-11-2023	Months Rs.25,000/-		
61.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	PureVision®2 for Presbyopia (Balafilcon A) Visibility Tinted Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 36 Months Rs.25,000/-	Soft Corrective Contact Lenses, Extended wear, Therapeutic Contact Lens (Balafilcon A) (disposable single use or for extended wear for 1-30 days)	**Approved** subject to provision of valid FQA, Readable labels.
62.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	Ultra® for Astigmatism (Samfilcon A) Visibility Tinted Soft Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 60 Months Rs.25,000/-	Samfilcon A Soft Contact Lenses (disposable single use or for extended wear for 1-30 days)	**Approved** subject to provision of valid FQA, Readable labels.
63.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	PureVision®2 for Astigmatism (Balafilcon A) Visibility Tinted Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 36 Months	Soft Corrective Contact Lenses, (Balafilcon A) (disposable single use or for extended wear for 1-30 days)	**Approved** subject to provision of valid FQA, Readable labels.

			Rs.25,000/-		
64.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	PureVision®2 (Balafilcon A) Visibility Tinted Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 36 Months Rs.25,000/-	Soft Corrective Contact Lenses, (Balafilcon A). (disposable single use or for extended wear for 1-30 days)	**Approved** subject to provision of valid FQA, Readable labels.
65.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	Ultra® (Samfilcon A) Visibility Tinted Soft Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 60 Months Rs.25,000/-	Samfilcon A Soft Contact Lenses (disposable single use or for extended wear for 1-30 days)	**Approved** subject to provision of valid FQA, Readable labels.
66.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb – IOM S.p.A., Via Pasubio 34, 20846 Macherio (MB), Italy FSC Italy Issuance 05-07-2019	Bausch + Lomb Biotrue Multi-Purpose Solution Class C Shelf Life: 24 Months 60ml, 120ml, 300ml **Rs.50,000/-**	Multi-Purpose Contact Lens Care Solution	**Approved** subject to provision of Readable labels.
67.	-do- **Evaluator:** Shahid	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY	Biotrue® Oneday for Presbyopia (Nesofilcon A) Visibility Tinted Contact Lenses	Soft Corrective Contact Lenses, daily Disposable (Nesofilcon A)	**Approved** subject to provision of valid FQA, Readable labels.

	Muhammad Iqbal	USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland Unit 424/425, Contact Lens Division Industrial Estate, Cork Rd Waterford, Munster, Ireland FSC USFDA Valid Till 29-08-2020	Pack Sizes (5s, 30s) Class B Shelf Life: 60 Months Rs.25,000/-	(single use disposable wear)	
68.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland Unit 424/425, Contact Lens Division Industrial Estate, Cork Rd Waterford, Munster, Ireland FSC USFDA Valid Till 29-08-2020	Biotrue® Oneday for Astigmatism (Nesofilcon A) Visibility Tinted Contact Lenses Pack Sizes (5s, 30s) Class B Shelf Life: 60 Months	Single use disposable wear Soft Corrective Contact Lenses, (Nesofilcon A).	**Approved** subject to provision of valid FQA, Readable labels.
69.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland Unit 424/425, Contact Lens Division Industrial Estate, Cork Rd Waterford, Munster, Ireland FSC USFDA Valid Till 29-08-2020	Biotrue® Oneday (Nesofilcon A) Visibility Tinted Contact Lenses Pack Sizes (5s, 30s, 90s) Class B Shelf Life: 60 Months Rs.25,000/-	Single use disposable wear Soft Corrective Contact Lenses, (Nesofilcon A)	**Approved** subject to provision of valid FQA, Readable labels.

70.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland Unit 424/425, Contact Lens Division Industrial Estate, Cork Rd Waterford, Munster, Ireland FSC USFDA Valid Till 29-08-2020	Soflens® 66 Toric (Alphafilcon A) Contact Lenses Pack Sizes (1s, 6s) Class B Shelf Life: 60 Months Rs.25,000/-	Daily wear or extended wear 1-7 days Alphafilcon Soft Contact Lenses	**Approved** subject to provision of valid FQA, Readable labels.
71.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s Bausch & Lomb Inc.1400 North Goodman street Rochester, NY USA 14609 FSC USFDA Valid Till 29-08-2020	Ultra® for Presbyopia (Samfilcon A) Visibility Tinted Soft Contact Lens Pack Sizes (1s, 6s) Class B Shelf Life: 60 Months Rs.25,000/-	Samfilcon A Soft Contact Lens (disposable single use or for extended wear for 1-30 days).	**Approved** subject to provision of valid FQA, Readable labels.
72.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Bausch & Lomb Inc. 1400 North Goodman street Rochester, NY USA 14609 **Manufacturing Site:** M/s Bausch & Lomb Ireland Unit 424/425, Contact Lens Division Industrial Estate, Cork Road, Waterford, Munster, Ireland FSC Ireland Valid Till 22-10-2023	Soflens 59 Soft Corrective Contact Lenses (hilafilcon) Pack Sizes (1s, 6s) Class B Shelf Life: 60 Months Rs.25,000/-	Soft corrective daily disposable contact lenses for short term use.	**Approved** subject to provision of valid FQA, Readable labels.

73.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi (ELI-00091) **Evaluator:** Hafiz Muhammad Asif Iqbal [1011]	**Legal Manufacturer:** Sofradim Production, 116 avenue du Formans, France (FSC FRANCE issue date 30-09-2016)	Parietene™Light weight Mesh Abdominal Hernia surgical Mesh, Synthetic Polymer, non-bio absorbable. Class C Shelf Life 5 Years. Codes /Sizes: (TCM1106, TCM1106X3, TCM1510, TCM1510X3, TCM1515, TCM11515X3, TCM2020, TCM2020X3, TCM3015, TCM3030, TCM4530) Rs.50,000/-	Parietene™flat and Lightweight Mesh is non-absorbable synthetic surgical mesh made out of two dimensional (2D) monofilament polypropylene knitted textile.	**Approved.**
74.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [994]	**Legal Manufacture:** Acon Laboratories, Inc. 10125 Mesa Rim Road San Diego, CA USA. **Contract Manufacturer:** AconBiotech (Hangzhou) Co., Ltd. No. 210 Zhenzhong Road West Lake District Hangzhou, Zhejiang China. FSC US FDA Valid till (25-12-2020)	On Call® Plus Blood Glucose Monitoring System Blood Glucose Monitoring System Class C Shelf Life: N/A Rs.50,000/-	On Call ®Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in fresh capillary whole blood sampled from the fingertip, palm, and /or forarm. For in vitro diagnostic use only. For self-testing and professional use.	**Approved** subject to provision of valid ISO 13485 Certificate
75.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [995]	**Legal Manufacture:** Acon Laboratories, Inc. 10125 Mesa Rim Road San Diego, CA USA. **Contract Manufacturer:**	On Call® PlusBlood Glucose Test Strips Blood Glucose Test Strips Class C	Blood Glucose Test Strips are the thin strips with a chemical reaent which work with the	**Approved** subject to provision of valid ISO 13485 Certificate and clarification of stability study.

		AconBiotech (Hangzhou) Co., Ltd. No. 210 Zhenzhong Road West Lake District Hangzhou, Zhejiang China. FSC US FDA Valid till (25-12-2020) FSC US FDA Valid till (25-12-2020)	Shelf Life: 24 Months Rs.50,000/-	on Call ® Plus Blood Glucose Meter to measure the glucose concentration In in whole blood.	
76.	**-do-** **Evaluator:** Hafiz Muhammad Asif Iqbal [1107]	**Legal Manufacturer:** PolysutureIndustria E ComercioLtda, Av. vereador Gabriel ramos da silva, 1245 Sao Sebastiao Do Paraiso –Mg CEP, 37950-000, BRASIL **Manufacturing Site.** PolysutureIndustriaComercioLtda, Brazil. (FSC Brazil Issuance 03-12-2018)	**COVIDIEN Bone Wax™ (Heamostatic Bone Wax)** Surgical Heamostatic Agents Class C Shelf Life: 3 Years Sizes & Codes: Bar: 50 mm (Length) x 20 mm (width) x 2.5 mm (Thickness), Stick : 25 mm (Length) x 11 mm (diameter) Rs.50,000/-	Bone Wax is indicated for use in the control of bleeding form bone surfaces.	**Approved** subjet to foreign inspection of manufacturer or provision of CE marked document. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
77.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1153]	**Legal Manufacturer:** Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone, 213022 Changzhou, China. (FSC Germany , Issued on 03-12-2018)	**KANGDI Disposable Skin Stapler** Class B Shelf Life :3 Years Sizes & Codes: KYPS-25R/KYPS-25W/KYPS-35R/KYPS-35W Rs.25,000/-	The Disposable Skin Stapler is mainly used for surgical stapling of superficial skin in human body wound and operative incision.	**Approved** subject to provision of proof of fee for the said product.
78.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1154]	**Legal Manufacturer:** Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone, 213022 Changzhou, China. (FSC Germany , Issued on 03-12-2018)	**KANGDI Sterile Disposable Circular Stapler** Class C Shelf Life: 3 Years Sizes & Codes: KYGW-21.5/KYGW-23.5/ KYGW-25.5/ KYGW-	The disposable Circular Stapler is mainly used for creation of end-to-end, end to side and side to side anastomosis in surgery of the alimentary	**Approved.**

			28.5/ KYGW-31.5/ KYGW-33.5/ KYWC-17.5/ KYWC-21.5/ KYWC-23.5/ KYWC-25.5/ KYWC-28.5/ KYWC-31.5/ KYWC-33.5/ KYWCL-21.5 KYWCL-23.5/ KYWCL-25.5/, KYWCL-28 .5/ KYWCL-31.5/ KYWCL-33.5 Rs.50,000/-	tract including esophagus, stomach and intestines. It can be used under the endoscope and in open operation.	
79.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1237]	**Legal Manufacturer:** Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone, 213022 Changzhou, China. (FSC Germany , Issued on 03-12-2018)	**KANGDIDisposable circular Stapler for Hemorrhoids** (Disposable Circular Stapler for Hemorrhoids) Class C Shelf Life: 3 Years Sizes & Codes: Disposable Circular Stapler for Hemorrhoids KYGZ-32/KYGZ-33.5, KYGZA-32, KYGZA-33.5, KYGZB-32, KYGZB-33.5, GCH32, GCH33.5, GCC32, GCC33.5,GCS32 , GCS33.5 Rs.50,000/-	The disposable Circular Stapler for Hemorrhoids is mainly used in the procedure for prolapse and hemorrhoids for IIIo ˷ IVo Hemorrhoids and rectal mucosa in tussusception..	**Approved.**
80.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planch-Ring 21 65205 Wiesbaden,	HUMAN **Testosterone 55010** Class B Shelf Life: 12 Months.	ELISA Test for the Quantitative Determination of Testosterone in Human Serum or Plasma	**Approved** subject to provision of valid Notarized ISO & FQA.

		Germany FSC Germany Issuance 21-11-2018	Rs.25,000/-		
81.	M/s. Siemens Healthcare Pvt Ltd., 4th Floor, State Life Building 15-A, Sir Agha Khan Road, Lahore. ELI-00146 **Evaluator:** Hafiz Muhammad Asif Iqbal [343-P]	**Manufacturer:** M/s. Siemens Medical Solutions USA, Inc., 2501 N. Barrington Road, Hoffman Estates, Illinois, 60192 USA. FSC USFDA Valid till May 07, 2021	**BiographmCT** BiographmCT S 20 Excel BiographmCT S (20) - 3R BiographmCT S (20) - 4R BiographmCTS (40) - 3R Biograph MCT S (40) - 4R BiographmCTS (64) - 3R BiographmCTS (64) - 4R BiographmCT X - 3R BiographmCT X - 4R BiographmCT Flow 20 - 3R BiographmCT Flow 20 – 4R BiographmCT Flow 40 - 3R BiographmCT Flow 40 – 4R BiographmCT Flow 64 - 3R BiographmCT Flow 64 – 4R BiographmCt Flow Edge - 3R BiographmCt Flow Edge – 4R Class C Service Life : 10 years Fee submitted: Rs. 50,000/-	PET / CT ScannerofDiagnostic Imaging System	**Approved subject to the opinion of Dr. Nadeem Ahmed, Radiologist Agha Khan Hospital, Karachi.**
82.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [344-P]	**Manufacturer:** M/s. Siemens Medical Solutions USA, Inc., 2501 N. Barrington Road, Hoffman Estates, Illinois, 60192 USA.	**Biograph Horizon** (PET / CT) Biograph Horizon Biograph Horizon – 3R Biograph Horizon	PET / CT Scanner for Diagnostic Imaging System	**-do-**

		FSC USFDA Valid till May 07, 2021	– 4R Class C Service Life : 10 years Fee submitted: Rs. 50,000/-		
83.	M/s The Searle Company Limited, 1st Floor, NICL Building, AbbasiShaheed Road, Karachi (ELI-00057) **Evaluator:** Hafiz Muhammad Asif Iqbal [1108]	**Legal Manufacturer** Jiangsu Shenli Medical Production Co., Ltd. 20, Changzheng Road, Zhenglu, Changzhou. (FSC China Valid till 05-05-2020)	**Searle Flo** Disposable Infusion Set with Needle Class B Shelf Life 36 Months (Sizes & Codes as Per FSC) IS-GB2, IS-GB4, IS-GB5, IS-GB7, IS-GB8, IS-GB9, IS-GE2, IS-GE9, With needle size (mm): 0.4*12RW SB, 0.45*15RW, SB, 0.5*20RW SB, 0.6*24TW SB, 0.9*28 TW SB, 1.1*28TW SB, 1.2*28TW SB	This product is suitable for human body intravenous gravity infusion for single use.	**Approved** subjet to foreign inspection of manufacturer or CE marked documents. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
84.	do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1106]	**Legal Manufacturer:** TG Meducak SDN BHD LOT 5091, JalanTeratai, Batu 5, Off JalanMeru, 41050 Klang, Selangor D.E. Malaysia. (FSCMalaysia Valid till 08-01-2024)	**Protiex** Sterile Latex Surgical gloves (Powder Free) Class B Shelf Life: 5 Years Sizes & Codes: Sterile Latex Surgical Gloves (Powder Free)/ ProTieX Code:GB8417368816 Rs.25,000/-	Sterile Latex Surgical gloves((Powder Free)	**Approved** subjet to foreign inspection of manufacturer provision of CE marked documents and valid & notarized Agency Agreement & ISO 13485 of the facility TG Meducak SDN BHD LOT 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the

					manufacturing plant. Valid & notarizes Agency Agreement required.
85.	M/s.Sadqain Health Care (Pvt) Ltd., Safari Villas 11,Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi. (ELI-00020) **Evaluator:** Hafiz Muhammad Asif Iqbal [373-P]	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**INTERSURGICAL Flexible Catheter Mount** (Catheter Mount) Class B Shelf Life:3 Years **Codes As per FSC:** Flexible fixed elbow Catheter Mount 22F – flip top cap with7.6mm port 22M/15F 170mm Rs.25,000/-	The device connected between the breathing system and the patient interface. A variety of different type spf breathing systamconncet ed to intersurgicalcat herter mounts via standar conical connections.	**Approved subject to** provision of 5 years data of stability study.
86.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [472-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 01-03-2016& 2nd FSC issued on 25-03-2019 containing variant 2830000 - 3L Reservoir Bag, 22F Neck	**INTERSURGICAL Reservoir Bag** Product Code – Name 2805000 - 0.5L Reservoir BagWith Anti Occlusion Cage Mount, 15F Neck , 2810000 - 1L Reservoir BagWith Anti Occlusion Cage Mount, 22F Neck, 2820000 - Reservoir Bag, 2L With Anti Occlusion Cage Mount, 22F Neck 2830000 - 3L Reservoir Bag, 22F Neck Class B	It is use to form a reservoir of respiratory gases as part of a breathing system.	**Approved.**

			Shelf Life : 05 years		
87.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [471-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 01st March, 2016	**INTERSURGICALFlextube Breathing System** (Flextube Breathing System) **Product Code – Name** 4510000 – 10mm Flextube B/S with Monitor Line and Water Traps and 0.8m Limb, 1.6m 4503000 – 15mm Flextube B/S with Water Traps, Ported Y-Piece and 0.4m Limb, 1.6m Class B Shelf Life : 05 years Rs.25,000/-	It is used to deliver and remove respiratory gases from a patient via a system of tubing and connectors.	**Deferred** for provision of 5 years data of stability study.
88.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [470-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 25th March, 2019	**INTERSURGICALSentri Adult Nssal Cannula** (Nasal Cannula) **Product Code – Name** 114401 – Sentri, Adult, Nasal Cannula with Curved Prongs and Tube, 2.1m 114402 – Sentri, Adult, Nasal Cannula with Curved Prongs CO_2 Monitoring Line, Filter and Tube, 2.1m Class B Shelf Life : 05 years Rs.25,000/-	It is used to deliver oxygen into the patient's nose.	**Deferred** for provision of stability data.
89.	-do- **Evaluator:** Hafiz Muhammad	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire,	**INTERSURGICALCOMPACT BREATHING SYSTEM**	It is use to deliver and remove anaesthetic and respiratory	**Approved.**

	Asif Iqbal [473-P]	United Kingdom. FSC U.K (MHPRA) Issued on 01st March, 2016	**Product Code – Name** • 2150000 – 22mm Compact, Extendable breathing system with luer elbow,1.5m • 2151000 - 22mCompact, Extendable breathing system with luer elbow,2.0m • 2154000- 22mm Compact, extendable breathing system with 2L bag and 1.5m limb, 2.0m • 2157000- 22mm Compact, breathing system with 2L bag and 2.0m limb, 3.0m • 2161000 - 15mm compact,paediatricextendable breathing system with luer elbow,1.5m • 2164000 - 15mm compact paediatricextendablebreathing system with luer elbow, ,	gases from a patient via a system of tubing and connectors.	

			1Lreservoir bag and 1.5m limb, 2m Class B Shelf Life : 05 years Rs.25,000/-		
90.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [469-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 25th March, 2019	**INTERSURGICALFLO-GUARD BREATHING FILTER** (Breathing Filter) Class B Shelf Life : 05 years Codes/Sizes: 1690000 Rs.25,000/-	It is used to reduce microbial transmission in respiratory systems and reduce bacterial and viral contamination of patients, medical devices and equipment.	**Approved** subject to provision of stability data.
91.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [468-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 1st March, 2016	**INTERSURGICALPaediatric high concentration Oxygen Mask** (High Concentration Oxygen Mask) Class B Shelf Life : 05 years Codes: Paediatric high concentration Oxygen Mask 1192000 Rs.25,000/-	High Concentration Oxygen Mask	**Approved** subject to provision of 5 years data of stablity study.
92.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [470-P]	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 25th March, 2019	**Sentri Adult Nsal Cannula** (Nasal Cannula) **Product Code – Name** 114401 – Sentri, Adult, Nasal Cannula with Curved Prongs and Tube, 2.1m 114402 – Sentri, Adult, Nasal Cannula with	It is used to deliver oxygen into the patient's nose.	**Approved.**

			Curved Prongs Co2 Monitoring Line, Filter and Tube, 2.1m Class B Shelf Life : 05 years Rs.25,000/-		
93.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [376-P]	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**Cirrus 2 Nebuliser, , IntersurgicalEcolite Mask Kit and Tube,** Nebuliser with mask Class B Shelf Life 3 Years Code: Cirrus 2 Nebuliser, adultIntersurgical Ecolite Mask Kit with Tube Code:1453015 Rs.25, 000/-	It is use to convert a liquid drug into a mist to enable a patient to inhale and deposit the drug in the lungs.	**Approved.**
94.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [367-P]	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**INTERSURGICAL Anaesthetic Breathing System (Mapelson)** **Class B** Shelf Life: 2105000: 3 Years 2121000 :5 years **Product Code – Name** 2105000- A Magileanaesthetic breathing system with 2L bag, 1.6m 2121000- Mapelson F Jackson Rees modification T piece breathing system with 0.5L open tail bag, 1.8m	It is use to deliver and remove anaesthetic and respiratory gases from a patient via a system of tubing and connectors.	**Approved.**
95.	-do-	Legal Manufacturer:	**Ecolite™ Adult Tracheosomy**	It is use to deliver	**Approved** subject to provision of valid

	Evaluator: Shahid Muhammad Iqbal	M/s. Intersurgical Limited. Address: , Crane House Molly Millars Lane, Wokingham, Berkshire, United Kingdom Manufacturing Site: UAB Intersurgical Arnioniu 60, Pabrade, LT-18170, Lithuania FSC UK Issuance 25.03.2019	**Mask** **Code: 1200050** Class B Shelf Life 05 years Rs.25,000/-	respiratory aerosol and oxygen to a patient	FQA.
96.	-do- **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer: M/s. Intersurgical Limited. Address: , Crane House Molly Millars Lane, Wokingham, Berkshire, United Kingdom Manufacturing Site: Well Lead Medical co., Ltd No. 47, Guomao Avenue South, Hualong, Panyu, Guangzhou, China FSC UK Issuance 25.03.2019	**Interguide Tracheal Tube Introducer Bougie** **8070006** **8070010** **8070015** CLASS B Shelf life 5 years Rs.25,000/-	It is used to aid intubation by guiding and shaping airway devices.	**Approved** subject to provision valid FQA and ISO for manufacturer in China.
97.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Intersurgical Limited. Address: , Crane House Molly Millars Lane, Wokingham, Berkshire, United Kingdom **Manufacturing Site:** UAB Intersurgical Arnioniu 60, Pabrade, LT-18170, Lithuania	**Intersurgical Oxygen recovery kit, 40 % oxygen** **1040013** Class B Shelf Life 05 years Rs.25,000/-	To provide spontaneously breathing, intubated patients with supplementary oxygen during transport and in the Recovery Room.	**Approved** subject to provision of valid FQA.

		FSC UK Issuance 25.03.2019			
98.	M/s Muslim Trading Agencies, 3 Syed Moj Darya Road, Lahore. (ELI-00359) **Evaluator:** Hafiz Muhammad Asif Iqbal [394-P]	**Legal Manufacturer:** Randox Laboratories Limited, 55the Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom (FSC UK Issue Date: 24-05-2018	**Bovine Chemistry Precision Controls** (Bovine Chemistry Precision) Class- C Shelf Life: 48 Months Code : SN1085 Bovine Chemistry Precision(C) Level 2 Code : SE1086 Bovine Chemistry Precision(control) Level 3 Rs.50,000/-	This product is intended for in vitro diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of multiple analytes listed in the package insert.	**Approved.**
99.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. (ELI-00209) **Evaluator:** Hafiz Muhammad Asif Iqbal [367-P]	**Legal Manufacturer:** DemedtitecDiagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance 13-03-2019)	DEMEDITEC Androstenedione ELISA KIT DEMEDITEC Dihydrotestosteron e ELISA KIT DEMEDITEC Testosterone free Androstenedione ELISA Dihydrotestostero ne ELISA Testosterone free Class B Shelf Life: 9 Months Codes As per FSC Rs.25,000/- DE3265 Androstenedione ELISA DE2330 Dihydrotestostero ne ELISA DE2924 Testosterone free	**The DEMEDITEC Androstenedio ne ELISA** is an enzyme immunoassay for the quantitative in vitro diganostic measurement of Androsternedi one is serum and EDTA plasma.	**Deferred** as the **f**irm has applied three ELISA Kits as a Cluster.

100	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [370-P]	**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 determinatio of Creatinine (creat) in capillar, venous, and arterial whole blood.	**Deferred** for provision of Embassy attested Free Sale Certificate.
101	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [367-P]	**Legal Manufacturer:** Demedtitec Diagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance13-03-2019)	**DEMEDITECA ndrostenedione ELISA Dihydrotestoster one ELISA Testosterone free** Androstenedione ELISA Dihydrotestostero ne ELISA Testosterone free Class B Shelf Life: 9 Months Codes : DE3265 Androstenedione ELISA DE2330 Dihydrotestostero ne ELISA DE2924 Testosterone free Rs.25,000/-	**The DEMEDITEC Androstenedio ne ELISA** is an enzyme immunoassay for the quantitative in vitro diganostic measurement of Androsternedi one is serum and EDTA plasma.	**Deferred** The firm applied three IVD kits in one application as Cluster. Androstenedione ELISA Dihydrotestosteron e ELISA Testosterone free
102	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Demeditec Diagnostics GmbH, Lise-Meitner-StraBe 2, D-24145 Kiel, Germany. (FSC Germany issued on 13-03-2019)	Mycobacterium Tuberculosis IgG (ELISA kit) Class C Shelf Life: 12 Months Ref No: DETUB01 96 wells Fee submitted: Rs. 25,000/-	Enzyme immunoassay for the detection and quantitative determination of human IgG antibodies against Mycobacteriu m tuberculosis in serum and plasma	**Approved.**
103	-do-	**Manufacturer:** Demeditec Diagnostics GmbH, Lise-Meitner-	Mycobacterium Tuberculosis IgM (ELISA kit)	Enzyme immunoassay for the	**Approved.**

	Evaluator: Ms. Unum Zia Shamsi	StraBe 2, D-24145 Kiel, Germany. (FSC Germany issued on 13-03-2019)	Class C Shelf Life: 12 Months Ref No: DETUB03 96 wells Fee submitted: Rs. 25,000/-	detection and quantitative determination of human IgM antibodies against Mycobacteriu m tuberculosis in serum and plasma	
104	M/s Flowtronix Systems, Flat No. 02 Al –Ashraf Plaza, range Road, Rawalpindi. (ELI-00217) **Evaluator:** Hafiz Muhammad Asif Iqbal [424-P]	**Legal Manufacturer:** Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Flex line Venous Catheter** (Venous Catheter) Class B Shelf Life: 5 Years Codes/Sizes: Flex Line Venous Catheter, Straight, reinforced with lighthouse tip. 01V201L8, 01V221L8, 01V241L8, 01V261L8, 01V281L8, 01V301L8, 01V321L8, 01V341L8, 01V361L8, Rs.25,000/-	The device is used to drain venous blood from right atrium and caval veins.	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-
105	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [410-P]	**Legal Manufacturer:** Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Aortic Root Cannulae** Class B Shelf Life: 5 Years Codes/Sizes: Aortic root cannula with vent line ARC02 ARC05 ARC08 ARC10 Rs.25,000/-	The device used for antegrade delivery of cadioplegia solution and for venting of the heart during cardiopulmona ry bypass surgery up to six hours or less. The cannula may also be used to aspirate air from the aorta at the conclusion of	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-

				the cardiac procedure.	
106	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [418-P]	**Legal Manufacturer:** Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Retrograde CardioplegiaCannulae** Class B Shelf Life: 5 Years Codes/Sizes: Retrograde CardioplegiaCannulae RCC01 Rs.25,000/-	The retrograde cardioplegia cannula is intended to be connected to the cardioplegi line for delivery of cardio pleagia solutions and blood into the patients coronary sinus during cardiopulmonary bypass procedures.	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-
107	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [422-P]	**Legal Manufacturer:** Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Flex line two stage venousCatheter** Class B Shelf Life: 5 Years Codes/Sizes: Flex Line Two Stage Venous Catheter, Proximal and Distal Reinforced with Light house Tip, with Connector. 01V32L401, 01V34L401, 01V34L461, 01V36L461, 01V36L511, Rs.25,000/-	The device used in venous draingae via the right atrium and inferior vena vavasimultenously during cardiopulmonary by pass surgery up to six hour or less.	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-
108	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [414-P]	**Legal Manufacturer:** Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Rigid Sucker** Class B Shelf Life: 5 Years Codes/Sizes: Rigid Sucker) RS01 Rs.25,000/-	The rigid sucker is an accessory for blood aspiration during cardiovascular surgery and cannulation. The device is used by a cardiovascular	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-

				surgeon during cardiovascular intervention.	
109	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [423-P]	**Legal Manufacturer:** Andocor NV-Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Aortic Catheter** Class B Shelf Life: 5 Years Codes/Sizes: Aortic Catheter, with luer connector with vent cap. AC201342V, AC221342V, AC201342VFL, AC241342V, AC241342VFL AC241342VH, AC241342VHS, AC241342VW, AC241342VH, AC261342V, AC301342V. Rs.25,000/-	The catheter is intended for use in perfusion of the ascending aorta during Cardiopulmonary bypass.	**Approved** as Class-D medical devices subject to submission of differential fee of Rs. 25,000/-
110	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [411-P]	**Legal Manufacturer:** Andocor NV-Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCO Arterial Cannulae** Class B Shelf Life: 5 Years Codes/Sizes: A20162V, B20162V, B20163V, A22162V, B22163V, A24162V, B24162V, B24163V. Rs.25,000/-	Thearterial cannulae use in perfusion of the ascending aorta during Cardiopulmonary bypass.	**Approved.**
111	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [421-P]	**Legal Manufacturer:** Andocor NV-Kwikaard 104 -2980 Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	**ANDOCOR Vent Catheter** Class B Shelf Life: 5 Years Codes/Sizes: PVC Vent Catheter, closed tip, straight PVSBG170 PVSBG 171	The device used in venting the left heart during cardiopulmonary bypass surgery up to six hours or less.	**Approved.**

			PVSBG 172 PVSBR170 PVSBR 171 PVSBR 172 PVSB180 PVSB181 PVSB182 PVSBG180 PVSBG181 PVSBG182 PVSBR180 PVSBR181 PVSBR182 PVSBI181 PVSB201 PVSBG201 PVSBR201 Rs.25,000/-		
112	M/s United International, GNB-F 18/A Ground Floor, F-Block, Mehar Sons Estate, Karachi. (ELI-00061) **Evaluator:** Hafiz Muhammad Asif Iqbal [1166]	**Legal Manufacturer:** Jiangsu Kangyou Medical Instrument Co., Ltd. Tangzhuang ,Yaotang Town 213223 Jiantan/ Jiangsu China. Provided Export Only Certificate from China.	Jazz Sterile Hypodermic Needles Sterile Hypodermic Needles Class B Shelf Life: 5 Years Codes/Sizes: 31G, 30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G, 16G, 15G. Rs.25,000/-	It is used by medical institutions to give patients intra muscular injection and pharmaceutical solutions, used with syringes. In addition, it can be used in conjunction with other instruments that need to input the drug solution into the vein.	**Approved** subjet to foreign inspection of manufacturer or provision of CE marked documents and provision of Embassy attested Free Sale Certificate, Stability Study protocol and data**.** The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
113	M/s Usmanco International, 220, Block: 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** Bicakcilar Global TibbiChazlarsanayiGazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC valid 11-08-2017)	BCAT2 I.V Cannula With injection port Class B Shelf Life: 5 Years (Sizes & Codes as Per FSC) **BCAT2 I.V Cannula With injection**	Single use, Sterile, over the needle peripheral intravascular catheter designed for the introduction or withdrawal of liquids into or	**Approved** subjet to foreign inspection of manufacturer**.** The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing

	[1167]		**port** **Ref: 01404181** **Rs.25,000/-**	from the peripheral vascular system injection port option with one way valve and color coded cap for intermittent and safe administration of drug infusion.	plant. The firm should submit valid FSC.
114	M/s Parazelsus Pakistan Private Limited, Office No. 201-204, 2nd Floor, Park Tower Shahrah-e-Firdousi, Block-5, Clifton, Karachi. (ELI-00340) **Evaluator:** Hafiz Muhammad Asif Iqbal [1213]	**Legal Manufacturer:** M/s SIFI S.p.A, SIFI S.p.A, via Ercole Patti n. 36, Laninaio-AciS.Antonio, CT 95025 Italy. (FSCItaly Issuance date 23-05-2018)	**Mini Well Toric Ready** (Intraoccular Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini Well Toric Ready Intraoccular Lens (IOL) X7560CZNNNNNA Rs.50,000/-	Intraoccular Lens (IOL)	**Approved** subject to provision of original and attested documents, duly filled Form 7A and Stability data.
115	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1212]	**Legal Manufacturer:** M/s SIFI S.p.A, SIFI S.p.A, via Ercole Patti n. 36, Laninaio-AciS.Antonio, CT 95025 Italy. (FSC Italy Issuance date 23-05-2018)	**Mini 4 Ready** Intraocular Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini 4 Ready Intraocular Lens (IOL) S/T7560CZYXXXA Rs.50,000/-	Intraocular Lens (IOL)	**Approved** subject to provision of duly filled Form 7A and Stability data.
116	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1211]	**Legal Manufacturer:** M/s SIFI S.p.A, SIFI S.p.A, via Ercole Patti n. 36, Laninaio-AciS.Antonio, CT 95025 Italy.	**Mini Well Ready**Intraocular Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini Well Ready	Intraoccular Lens (IOL)	**Approved** subject to provision of dually filled Form 7A and Stability data.

		(FSC Italy Issuance date 23-05-2018)	Intraoccular Lens (IOL) Z7560CZNNNNNA Rs.50,000/-		
117	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1210]	**Legal Manufacturer:** M/s SIFI S.p.A, SIFI S.p.A, via Ercole Patti n. 36, Laninaio-AciS.Antonio, CT 95025 Italy. (FSC Italy Issuance date 23-05-2018)	**Mini Toric Ready**Intraoccular Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini Toric ReadyIntraoccular Lens (IOL) V7560CZNNNNNA Rs.50,000/-	Intraoccular Lens (IOL)	**Approved** subject to provision of dually filled Form 7A and Stability data.
118	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1214]	**Legal Manufacturer:** M/s SIFI S.p.A, SIFI S.p.A, via Ercole Patti n. 36, Laninaio-AciS.Antonio, CT 95025 Italy. (FSC Italy Issuance date 23-05-2018)	**Mini 2 Ready** Intra ocular Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini 2 Ready Intra ocular Lens (IOL) R2560CZPNNNNA Rs.50,000/-	Intra ocular Lens (IOL)	**Approved** subject to provision of dually filled Form 7A and Stability data.
119	M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi (ELI-00029) **Evaluator:** Hafiz Muhammad Asif Iqbal [1169]	**Legal Manufacturer:** Ameco Medical Industries, Industrial Zone B4-Part 119 East 10th of Ramadan City, Egypt. (FSC Egypt Valid till26-11-2022)	**Amecath** Double Lumen Loop Ureteral Stent with catheter pusher with two clamps Urology catheters kits Class C Shelf Life: 36 Months Sizes & Codes: Not provided	Double lumen Ureteral Stent is a single use device made of radiopaque polyurethane intended for temporary internal drainage from the renal pelvis to the bladder.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents.
120	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1168]	**Legal Manufacturer:** Ameco Medical Industries, Industrial Zone B4-Part 119 East 10th of Ramadan City, Egypt. (FSC Egypt Valid till26-11-2022)	**Amecath** Short Term Haemodialysis catheter Kits Dialysis catheters Kits Class B Shelf Life: 36 Months	Amecath Short Term hemodialysis is a sterile single use device indicated for use in attaining short term access for	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents.

			Sizes & Codes: Short Term heamodialysisstep tip kit Catheter. 285/2017/1 Rs.25,000/-	Hemodialysis or apheresis.	
121	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) **Evaluator:** Hafiz Muhammad Asif Iqbal [1162]	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSC valid 10-07-2021)	Hamilton-G5 (Intensive Care Ventilator) Class C Life: 8 Years Sizes & Codes: Hamilton-G5 159005 Rs.50,000/-	The Hamilton-G5 Ventilator is designed for intensive care ventilation of adult and pediatric patient, and optionally infant and neonatal patient.s The device is intended for use in the hospital institutional environment where health Care professionals provide patient care. Intended use Hamilton-G5/S1Ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.	**Approved.**
122	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1163]	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSCSwitzerlandvalid till 10-07-2021)	Hamilton-T1 (Intensive Care Ventilator) Class C Life: 8 Years Sizes & Codes: Hamilton-T1 161006, 161009	The Hamilton-T1 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics, and optionally	**Approved.**

				infants and neonates. Intended areas of use: In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room. For emergency medical care, during transport within and outside the hospital. During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship.	
123	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1157]	**Legal Manufacturer:** TOP Corporation, 19-10 SenjuNaki-Cho, Adachi-ku, Tokyo, Japan. **Manufacturing Site:** TOP Corporation Koshigaya Factory 40-34 Noborito-cho, Koshigaya-Shi, Saitama, Japan (FSC, Japan, issuance date 21-11-2018)	TOP-5520 (Syringe Pump) Class C Life: 6 years Sizes & Codes: N/A Rs.50,000/-	Pole Clamp, Drop Sensor, Multiple pump Mount, stand, Nurse call cable, drop sensor holder, Operating Guide, AC Power cable, DC Power cable.	**Approved** subject to provision of Essential principles of safety and performance.
124	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1161]	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSCSwitzerland valid till 10-07-2021)	Hamilton-C1 Intensive Care Ventilator Class C Shelf Life: N/A (Sizes & Codes as Per FSC) Hamilton-C1 161001 Rs.50,000/-	The Hamilton-C1 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics and optionally	**Approved** subject to provision of valid Full Quality Assurance System Certificate.

				infants and neonates. Intended use: In the intensive a care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room. Hamilton-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specification.	
125	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1160]	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSCSwitzerland valid till 10-07-2021)	Hamilton-C3 (Intensive Care Ventilator) Class C Life: 8 Years Sizes & Codes: 160005, 160006 Rs.50,000/-	The Hamilton-C3 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics and optionally infants and neonates. Intended use: In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in	**Approved.**

				the recovery room. During transfer of ventilated patient with in the hospital. Hamilton-C3 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specification.	
126	M/s Novo Nordisk Pharma (Pvt) Ltd, 113, Shahrah e Iran, Clifton, Karachi. (ELI-00264 & 30) **Evaluator:** Hafiz Muhammad Asif Iqbal [1122]	**Legal Maufacturer:** Novo Nordisk A/S Novo Alle 2880 Bagsvaerd Denmark. **Manufacturing Site For Following sizes: (NovoFine 30G NovoFine 31G NovoFine 32G 0.23/0.25×6mm)** Nipro (Thailand) Corporation Limited 10/2 Moo 8, Bangnomko, Sena, PhraNakhon Si Ayuthaya 13110 Thailand. **Manufacturing Site For Following sizes: (NovoFine 30G NovoFine 31G NovoFine 32G 0.23/0.25×6mm) NovoFine 32G 0.23/0.25×4mm)** Nipro medical	NovoFine® (Medication pen injector needle) Class B Shelf Life: 5 Years Sizes & Codes: NovoFine 30G, NovoFine 31G, NovoFine 32G 0.23/0.25×6mm), NovoFine 32G 0.23/0.25×4mm. Rs.25,000/-	NovoFine® needles are the designation for sterile hypodermic needles for single use .NovoFine® needles have a standard thread interface with the pen injectors, in accordance with ISO 116028-2:2012 (16)	**Approved.**

		Industries LTD. Tatebayashi Plant 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 274-8518 JAPAN. (FSC Denmark Issuance Date 28-06-2020)			
127	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator:** Hafiz Muhammad Asif Iqbal [1125]	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany (FSC Germany issuance date 12-04-2019)	Certofix Quattro (Central Venous Catheter) Class D Shelf Life: 5 Years Sizes & Codes: 4167767-07, 4167775-07, 4167783-07 Rs.50,000/-	The Central Venous catheter set used for catheterization of the superior vena cava using the Seldinger technique.	**Approved** subject to provision of realtime Stability data for 5 years shelf life.
128	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1128]	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany (FSC Germany issuance date 12-04-2019)	CertofixQuinto (Central Venous Catheter) Class D Shelf Life: 5 Years Sizes & Codes: 4166841-07, 4166852-07, 4166868-07 Rs.50,000/-	The Central Venous catheter set used for catheterization of the superior vena cava using the Seldinger technique.	**Approved.**
129	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1126]	**Legal Manufacturer:** Stockert GmbH Botzinger Str. 72 79111 freiburg, Germany (FSC Germany issuance 25-01-2019)	Stimuplex HNS12 (Nerve Stimulator) Class B Shelf Life: N/A (Sizes & Codes as Per FSC) Stimuplex HNS12 DE/CA39/04/044/005A Rs.25,000/-	The nerve stimulator is intended for localization of nerves in peripheral regional anesthesia. Under no circumstances may it be used on a patient undergoing surgery.	**Deferred** for provision of preliminary test data and clinical study data.
130	-do-	**Legal Manufacturer:**	Stimuplex HNS Compact	Stimuplex @ Compact is	**Deferred** for provision of

	Evaluator: Hafiz Muhammad Asif Iqbal [1127]	Stockert GmbH Botzinger Str. 72 79111 freiburg, Germany (FSC Germany issuance 25-01-2019)	(Nerve Stimulator) Class B Shelf Life:N/A (Sizes & Codes as Per FSC) Stimuplex HNS Compact Code: 4892101 DE/CA39/1375/A03 Rs.25,000/-	used during preoperative stimulation of nerve fibers in living organism for performing peripheral nerve blocks. The device is used in conjuction with specialized stimulation needles. The device generates predefined electrical pulses at the tip of the stimulation needle is placed sufficiently close to the target nerve the desired muscle contractions can be observed so that the physician can inject the anesthetic in the proximity of the nerve to achieve an effective nerve blocks.	preliminary test data and clinical study data.
131	M/s Kaumedex, E-14/2, New Super Town, Link-2, Defence Road, Lahore. (ELI-00162) **Evaluator:** Hafiz	**Legal Manufactuer:** M/s.Supermax Glove Manufacturing SDN. BHD. LOT 38,& 42 Putra Industrial Park, Bukit Rahman, Putra, 47000 Sungai Buloh, Selangor DarulEhsan, Malaysia.	**High-Max** (Latex Powdered Surgical Gloves) Codes/Sisez: SGLP 5.5 SGLP 6.0 SGLP 6.5 SGLP 7.0 SGLP 7.5 SGLP 8.0	Latex Powdered Surgical Gloves	**Approved** subject to inspection of foreign manufacturer and provision of Credentials of the manufacturer abroad, ISO 13485, Full Quality assurance and

	Muhammad Asif Iqbal [490-P]	FSC Malaysia Valid till 30.10.2019	SGLP 8.5 SGLP 9.0 Class : B Shelf Life: 5Years Rs.25,000/-		original Embassy attested. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
132	M/s. Global Health Care, Midway Commercial Plaza No. 20, BackSide of prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. (ELI-00086) **Evaluator:** Hafiz Muhammad Asif Iqbal [352-P]	**Legal Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSCKorea Issuance 22-10-2018)	**ichroma™Tn-I** Test for Cardiac Troponin-I Class C Shelf Life: 20 Months for Kit 12 Months for Control Codes As per FSC **ichroma™Tn-I** Product License No. 17-469 Classification: IVD reagents for cardiac maker.	**ichroma™Tn-I** is a Flourescence Immunoassay (FIA) for the quantitative determination of cardiac troponin-I (Tn-I) in human Serum/Plasma . It is useful as an aid in management and monitoring of acute myocardial infarction AMI. forinvitro diagnostic only.	**Approved** subject to foreign inspection of manufacturer. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
133	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 **Evaluator:** Hafiz Muhammad Asif Iqbal [438-P]	**Manufacturer** M/s. Atrium Medical Corporation, 40 Continental Blvd, Merrimack, NH 03054, USA. FSC USFDA Valid till December 06, 2019.	**Ocean** Chest Drain (Chest Drain single ATS bag compatible) Codes: 2002-000, 2002-040 Class B Shelf Life : 03 years Rs.25,000/-	The Ocean Chest drain for thoracic drainage is a dispoable, water seal operating system.	**Approved** subject to valid Embassy attested Free Sale Certificate.
134	-do-	**Legal Manufacturer:** CryoLife Inc., 1655 roberts Blvd. NW,	**On-X Ascending Aortic Prosthesis**	Aortic bi-leaflet heart valve	**Approved.**

	Evaluator: Shahid Muhammad Iqbal	Kennesaw, Georgia 30144, USA **Manufacturing Site:** On-X Life Technologies, Inc. 1300 East Anderson lane, Building B, Austin, TX 78752, USA FSC USA valid till 07-03-2020	Class D Shelf Life: 5 Years **On-X® Ascending Aortic Prosthesis** Codes: ONXAAP-19, ONXAAP-21, ONXAAP-23, ONXAAP-25, ONXAAP-27/29 Rs.50,000/-	prosthesis/biologic polymer aorta graft.	
135	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	M/s. Eurosets srl STRADA STATALE 12, n.143 41036 MEDOLLA (MO)ITALY. FSC Italy Issued on March 23, 2018.	SKIPPER STERILE (OXYGENATORS) Class B Shelf Life : 03 years Code: EU5007 Rs.25,000/-	The device specifically designed to perform the various cardiopulmonary bypass techniques.	**Approved** subject to provision of Agency Agreement, ISO 13485, Production QA certificate and Stability data & label.
136	-do- **Evaluator:** Hafiz Muhammad Asif Iqba	M/s. Eurosets srl STRADA STATALE 12, n.143 41036 MEDOLLA (MO) ITALY. FSC Italy Issued on March 23, 2018.	TRILLY FULL COATED STERILE (OXYGENATORS) Class B Shelf Life : 03 years Code: (AG5032) Rs.25,000/-	The device specifically designed to perform the various cardiopulmonary bypass techniques.	**Approved** subject to provision of Agency Agreement, ISO 13485, Production QA certificate and Stability data & label.
137	M/s. NwillHeathcare, Office No. B-9,	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1	**One Touch Lights Condom** (Natural Rubber Latex Male	Natural Rubber Latex Male Condom (Contraceptive	**Approved.**

	Royal Garden Hotel Building, 19-BirdwoodRoad , Lahore. (ELI-00164) **<u>Evaluator</u>:** Hafiz Muhammad Asif Iqbal [455-P]	Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand Issued on 13.05.2019 FSC Germany Issued on 26.04.2017	Condom) Class C Shelf Life: 5 years Rs.50,000/-	Device)	
138	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi20110, Thailand. FSC Thailand Issued on 13.05.2019 FSC Germany Issued on 26.04.2017	**One Touch** Classic**Condom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**
139	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon	**One Touch** Romantic **Condom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**

		Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand Issued on 13.05.2019 FSC Germany Issued on 26.04.2017			
140	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand Issued on 13.05.2019 FSC Germany Issued on 26.04.2017	**One Touch** Extra Safe **Condom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**
141	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand Issued on 13.05.2019	**One Touch Dotted Condom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**

		FSC Germany Issued on 26s			
142	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand Issued on 13.05.2019 FSC Germany Issued on 26.04.2017	**One Touch Ribbed Condom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**
143	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [455-P]	**Legal Manufacturer:** M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. **Manufacturing Site:** M/s. Thai Nippon Rubber Industry Public Company Limited, 789/139 Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Chonburi 20110, Thailand. Thailand Issued on 13.05.2019 FSC Germany Issued on 26	**One Touch Enjoy MaxxCondom** (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	**Approved.**
144	M/s HooraPharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park,	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:**	1. Versant® HCV Genotype 2.0 Assay (LipA) (SMN 10325052 REF	Siemens Versant HCV Genotype 2.0 Assay (LipA) is a line probe assay, for in vitro	**Approved** subject to provision of updated LOA.

	Karachi (ELI-00037) **<u>Evaluator</u>:** Shahid Muhammad Iqbal	Fujirebio N.V., Technologiepark 6, 9052 Gent Belgium (FSC UK valid till 31-12-2020)	06719382) Shelf life : 18 months 2. Versant® HCV Amplification 2.0 Kit (LipA) (SMN 10325050 REF 06718688) Shelf life : 20 months 3. Versant® HCV Control 2.0 Kit (LipA) (SMN 10325051 REF 06719269) Shelf life : 24 months Hapatitis C Virus Assay Class D Rs.50,000/-	diagnostic use, which identifies HCV. Siemens Versant HCVAmplification 2.0 Kit (LipA) Is designed for use in reverse transcription and amplification of the 5 untranslated regions (5'UTR) and core region of the Hepatitis C Virus genome. Siemens Versant HCV Control 2.0 Kit (LipA) is designed for use with the versant HCV amplification 2.0 Kit (LipA) and the versant HCV Genotype 2.0 assay (LiPA) products.	
145	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Manufacturing Site:** M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street Easz Walpole, MA, 02032, USA (FSC UK, Valid Till	Siemens Advia Centaur SYPH assay ADVIA Centaur Syphilis (SMN 10492493) ADVIA Centaur Syphilis Quality Control Material (SMN 10492616) Class C Shelf Life: 12 Months Rs.50,000/-	The Assay is an in vitro diagnostic immunoassay for the qualitative determination of antibodies to Treponema Pallidum in human serum or plasma.	**Approved.**

		31-12-2020)			
146	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Manufacturing Site:** M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street Easz Walpole, MA, 02032, USA (FSC UK, Valid Till 31-12-2020)	Siemens Atellica IM SYPH assay Atellica IM SYPH Quality Control (Syph QC) SMN 10995676 Atellica IM Syphilis (Syph) SMN 10995675 Class C Shelf Life: 12 Months Rs.50,000/-	The Assay is an in vitro diagnostic immunoassay for the qualitative determination of antibodies to Treponema Pallidum in human serum or plasma.	**Approved.**
147	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Authorized Representative:** M/s Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, PO Box 6101, Newark, DE, 19714, US FSC UK, Validity 03-05-2023	Dimension Cardiac Troponin I Flex reagent cartridge SMN 10464525 P/N RF621 Dimension LOCI Cardiac Troponin I Calibrator SMN 10464336 P/N RC621 Class: C Shelf Life: 10 Months Rs.50,000/-	The TNI Method is an in vitro diagnostic test for the quantitative measurent of cardiac troponin I in human serum and plasma.	**Approved** subject to provision of updated LOA, ISO for manufacturing and FQA or explanation.
148	M/s. Progressive Coporation, 147-D, Commerical Broadway, Phase -8 DHA, Lahore (ELI-00114) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s. Medica S.p.A, Via Degli Artigiani, 7 41036, Medolla (MO), Italy. FSC Italy Issued on 26.07.2018	**SMARTFLUX LFP. 140 PUERMA® M03534 SMARTFLUX LFP. 140 PUERMA®** Class C Shelf Life: 3 Years Rs.25,000/-	Hemodialysis filters	**Approved.**

149	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abbott GmbH & Co, KG, Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Denka seiken Co., Ltd., Kagamida Factory, 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, 959-1695, Japan FSC Germany Issuance 20-09-2018	ARCHITECT SCC **ARCHITECT SCC Calibrators 8D18-02** **ARCHITECT SCC Control 8D18-12** **ARCHITECT SCC Reagent Kit (100 Tests) 8D18-28** **ARCHITECT SCC Reagent Kit (2000 Tests) 8D18-38** Class C Shelf Life: 12 Months Calibrator & Controls: 24 Months Rs.50,000/-	Assay for the quantitative determination of Squamous cell carcinoma antigen (SCC Ag) in human serum and plasma to be used as an aid in the management of patients with squamous cell carcinoma.	**Approved.**
150	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abbott Laboratories Diagnostics Division 100 Abbott Park Rd. Abbott Park, IL USA 60064 **Manufacturing Site:** Denka Seiken Co., Ltd. (Kagamida Factory) 1359-1, Kagamida, Kigsohi Gosen-Shi, Niigata Japan. 959-1695 FSC USA validity 15-05-2020	ARCHITECT iphenobarbital **ARCHITECT iphenobarbital Calibrators 1P33-01** **ARCHITECT iphenobarbital Reagent Kit 1P33-25** Class C Shelf Life: 18 Months Rs.50,000/-	Assay for the quantitative measurement of Phenobarbital in human serum or plasma.	**Approved.**
151	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abbott Laboratories Diagnostics Division 100 Abbott Park Rd. Abbott Park, IL USA 60064 **Manufacturing Site:** Denka Seiken Co., Ltd. (Kagamida Factory) 1359-1, Kagamida,	ARCHITECT iPhenytoin **ARCHITECT iPhenytoin Calibrators 1P34-01** **ARCHITECT iPhenytoin Reagent Kit 1P34-25**	Assay for the quantitative measurement of phenytoin, anticonvulsant drug, in human serum or plasma on the ARCHITECT iSystem.	**Approved.**

		Kigsohi Gosen,-Shi, Niigata Japan. 959-1695 FSC USA Validity 15-05-2020	Class C Shelf Life: 18 Months Rs.50,000/-		
152	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Denka seiken Co., Ltd. Kagamida Factory, 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, 959-1695, Japan FSC Germany issuance 19-07-2018	ARCHITECT PIVKA-II **ARCHITECT PIVKA-II Reagent Kit 2P48-25** **ARCHITECT PIVKA-II Reagent Kit 2P48-35** **ARCHITECT PIVKA-II Calibrators 2P48-01** **ARCHITECT PIVKA-II Controls 2P48-10** Class C Shelf Life: Reagents: 17 months Calibrator and Controls: 23 months Rs.50,000/-	Quantitative determination of PIVKA-II in human serum or plasma.	**Approved.**
153	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abbott Laboratories Diagnostics Division 100 Abbott Park Rd. Abbott Park, IL USA 60064 **Manufacturing Site:** Denka Seiken Co., Ltd. (Kagamida Factory) 1359-1, Kagamida, Kigsohi Gosen,-Shi, Niigata Japan. 959-1695 FSC USA validity 15-05-2020	ARCHITECT iValproic Acid **ARCHITECT iValproic Acid Calibrator 1P35-01** **ARCHITECT iValproic Acid Reagent Kit 1P35-25** Class C Shelf Life: 18 Months Rs.50,000/-	Assay for the quantitative measurement of Valproic acid, in human serum or plasma.	**Approved.**

154	M/s. Optisurg 17- C-1, Valencia Town, Lahore. ELI-00305 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** M/s. Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA 5095, Australia. FSC Australia Issuance 18-12-2018	**Ellex Integre Pro™ Scan LP6RG Integre Pro Scan LP6RG** Class C Service Life: 07 years Rs.50,000/-	The Ellex Integer Pro Scan LP6RG is indicated for use in photocoagulation of both anterior and posterior segments of the eye including retinal and pan-retinal photocoagulation of vascular and structural abnormalities of the retina and choroid.	**Approved.**
155	M/s. Haji S. Ameer Din & Sons, 305-A, Upper Mall, Lahore. ELI-00059 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** M/s. Sonomed Inc. (dba Sonomed Escalon), 1979 Marcus Avenue, Suite C105, Lake Success, NY 11042, USA. FSC USFDA Valid till October 18, 2020	Ophthalmic Ultrasound Equipment **PacScan + Model 300A +** Class B Shelf Life: N/A Rs.25,000/-	PacScan™ 300 A+ is the latest generation ophthalmic biometry instrument. The A-Scan mode allows for measuring the axial length, anterior chamber depth and thickness of an eye for calculating the IOL power for an implanted lens.	**Approved.**
156	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** M/s. Sonomed Inc. (dba Sonomed Escalon), 1979 Marcus Avenue, Suite C105, Lake Success, NY 11042, USA. FSC USFDA Valid till October 18, 2020	Ophthalmic Ultrasound Equipment VuPad Model: VuPad A/B Class B Shelf Life: N/A Rs.25,000/-	Multifunctional ophthalmic ultrasound system capable of imaging of various ophthalmic structures with probes scanning the eye either through direct contact or	**Approved.**

				immersion methods.	
157	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** M/s. Sonomed Inc. (dba Sonomed Escalon), 1979 Marcus Avenue, Suite C105, Lake Success, NY 11042, USA. FSC USFDA Valid till October 18, 2020	Ophthalmic Ultrasound Equipment **PacScan + Model 300AP +** Class B Shelf Life: N/A Rs.25,000/-	PacScan™ Plus is the latest generation ophthalmic biometry instrument.	**Approved.**
158	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Sonomed Inc. 1979 Marcus Ave, Suite C105, Lake Success, NY USA 11042. FSC US FDA valid till 18-10-2020	VuPad U (Ophthalmic Ultrasound system) Class B Service Life: 7 years Fee submiited: Rs. 25,000/-	Intended to be used to visualize and measure the eye and orbit	**Approved.**
159	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Sonomed Inc. 1979 Marcus Ave, Suite C105, Lake Success, NY USA 11042. FSC US FDA valid till 18-10-2020	Master-Vu A-Scan(Ophthalmic Ultrasound System) Class B Model: MV4500 Service Life: 7 years Fee submiited: Rs. 25,000/-	Intended for use in ophthalmic applications, by measuring internal structures of eye along the visual axis.	**Approved.**
160	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Sonomed Inc. 1979 Marcus Ave, Suite C105, Lake Success, NY USA 11042. FSC US FDA valid till 18-10-2020	Master-Vu B-Scan(Ophthalmic Ultrasound System) Class B Model: MV5600 Service Life: 7 years Fee submiited: Rs. 25,000/-	Intended for use in ophthalmic applications, by imaging internal structures of eye.	**Approved.**
161	M/s. Tech Zone, 764 Askari 9, Zarar Shaheed Road, Cantt, Lahore, Ware House:	**Legal Manufacturer and Manufacturing Site:** M/s. Set Medikal, Instiklal Mah. Maresal Fevzi Cakmak Cad.	**SET ®** (Insulin Syringe) **0.3ML 3P Insuline sterile syringe**	Insulin Syringe is a medical device that is used to inject insulin into the body.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents.

	Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040 **Evaluator:** Shahid Muhammad Iqbal	No. 18 I 34522 Esenyurt Istanbul, Turkey. FSC Turkey Validity 4th May, 2020	**8699207331295** **8699207331301** **8699207331318** **0.5ML 3P Insuline sterile syringe** **8699207351309** **8699207351316** **8699207351293** **1ML Insuline sterile syringe** **8699207311266** **8699207311297** **8699207311310** Class B Shelf Life: 05 years Rs.25,000/-		The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
162	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s. Set Medikal, Instiklal Mah. Maresal Fevzi Cakmak Cad. No. 18 I 34522 Esenyurt Istanbul, Turkey. FSC Turkey Issued on 4th May, 2017	**SET ®** (Disposable Syringe) 1ML, 2ML, 3ML, 5ML, 10ML, 20ML, 50ML, 60ML WITH 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G, 31G NEEDLES. Class B Shelf Life: 05 years	Disposable Syringe is a medical device that is used to inject fluid into or withdraw fluid from the body.	**Approved only 1ml, 10 ml, 20ml, 50ml and 60ml.**
163	M/s Fresenius Kabi, Pakistan (Pvt) Ltd. First Floor, Tanwir Ahmad Medical Center (TAMC), MM Alam Road, 27-C/3, Gulberg III, Lahore ELI- 00266	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance	**Agilia SP PCA WIFI IN Z020197** Class C Service Life: 10 years Rs.50,000/-	Infusion IV Pump	**Approved subject to confirmation of original documents.**

	Evaluator: Shahid Muhammad Iqbal	11th January, 2019			
164	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	**Agilia SP TIVA WII IN** **Z018997** Class C Service Life: 10 years Rs.50,000/-	Infusion IV Pump	**Approved.**
165	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	**Agilia SP MC IN** **Z018697** Class C Service Life: 10 years Rs.50,000/-	Infusion IV Pump	**Approved.**
166	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	**Agilia SP MC WIFI IN** Reference :Z018797 **Class C** Service Life: 10 years Rs.50,000/-	Infusion IV Pump	**Approved**.
167	-do- **Evaluator:** Shahid Muhammad	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany	**Agilia VP MC WIFI IN** **Z019797** Class C Service Life: 10	Infusion IV Pump	**Approved**.

	Iqbal	**Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	years Rs.50,000/-		
168	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	**Agilia VP MC WIFI IN** Reference :Z019797 **Class C** Service Life: 10 years Rs.50,000/-	Infusion IV Pump	**Approved**.
169	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany **Manufacturing Site:** Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11th January, 2019	**Agilia VP IN** Reference :Z019597 Class C Service Life: 10 years Rs.50,000/-.	Infusion IV Pump	**Approved**.
170	M/s. Bristol Mayer Biotech Pakistan (Pvt) Ltd, 73-B, Guldasht Town, Zarar Shaheed Road, Lahore. ELI-00093 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer :** M/s. Dr. Arabin GmbH & Co., KG, Alfred Herrhousen Str. 44 58455, Witten, Germany. FSC Germany issued on 14.02.2018	Arabin® Cerclage Pessary Type A (non-perforated) Class C Sizes: 70/21/32 70/17/35 70/17/32 65/25/35 65/25/32 65/21/35 65/21/32 65/17/35 65/17/32	Silicone pessary used to treat pregnant women with cervical incompetence in order to support the cervix and turn it towards the sacrum.	**Approved**.

			(sizes not on FSC. Manufacturer has provided dimenison certificate for the above products manufactured by them) Shelf Life: 10 years Fee submiited: Rs. 50,000/-		
171	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer :** M/s. Dr. Arabin GmbH & Co., KG, Alfred Herrhousen Str. 44 58455, Witten, Germany. FSC Germany issued on 14.02.2018	Arabin® Cerclage Pessary Type ASQ (Perforated) Class C Sizes: 70/25/35 70/25/32 70/21/35 70/21/32 70/17/35 70/17/32 65/25/35 65/25/32 65/21/35 65/21/32 65/17/35 65/17/32 (sizes not on FSC. Manufacturer has provided dimenison certificate for the above products manufactured by them) Shelf Life: 10 years Fee submiited: Rs. 50,000/-	Silicone pessary used to support the cervix in pregnant patients with threatening preterm labor (Funneling / short cervical length). The perforation allows drainage of discharge.	**Approved** subject to provision of EPSP.
172	M/s. Elite Traders, House No. B-342,B-Block, Satellite Town, Rawalpindi. (ELI-00193) **Evaluator:** Ms. Unum Zia Shamsi	**Manufactuer:** M/s. Implantcast GmbH, Luneburger Schanze 26, D-21614, Buxtehude, Germany. FSC Germany issued on 07.03.2019	ACS® Knee System Class D Codes: **ACS® SC femoral component cemetless pc** 42004202 2L 42004208	A total knee replacement that consists of numerous components designed to resurface the articulating surface of the femur, tibial	**Approved**.

			2,5L 42004203 3L 42004204 4L 42004205 5L 42004206 6L 42004212 2R 42004218 2,5R 42004213 3R 42004214 4R 42004215 5R 42004216 6R **ACS® SC femoral component cemented** 42004302 2L 42004308 2,5L 42004303 3L 42004304 4L 42004305 5L 42004306 6L 42004312 2R 42004318 2,5R 42004313 3R 42004314 4R 42004315 5R 42004316 6R **ACS® LD PS femoral component cemented** 42006102 2 left 42006103 3 left 42006104 4 left 42006105 5 left 42006106 6 left 42006108 2,5 left 42006112 2 right 42006113 3 right 42006114 4 right	and patellar.	

			42006115 5 right 42006116 6 right 42006118 2,5 right **ACS® PS femoral component cemented** 42006202 2L 42006203 3L 42006204 4L 42006205 5L 42006206 6L 42006208 2,5L 42006212 2R 42006213 3R 42006214 4R 42006215 5R 42006216 6R 42006218 2,5R **ACS® PS femoral component cementless pc** 42006602 2L 42006603 3L 42006604 4L 42006605 5L 42006606 6L 42006608 2,5L 42006612 2R 42006613 3R 42006614 4R 42006615 5R 42006616 6R 42006618 2,5R **ACS® LD PS femoral component cementless pc** 42009402 S 2left 42009408 S 2,5left 42009403 S 3left		

			42009404 S 4left 42009405 S 5left 42009406 S 6left 42009412 S 2right 42009418 S 2,5right 42009413 S 3right 42009414 S 4right 42009415 S 5right 42009416 S 6right **ACS® MB tibial component cemented** 42010212 2 42010213 3 42010214 4 42010215 5 42010216 6 42010217 7 42010219 3,5 **ACS® MB tibial component cementless cpTi/TCP** 42010202 2 42010203 3 42010204 4 42010205 5 42010206 6 42010207 7 42010209 3,5 **ACS® MB tibial component cementless pc** 42013102 2 42013103 3 42013104 4 42013105 5 42013106 6 42013107 7 42013109 3,5 **ACS® LD MB tibial component**		

			cemented 42010822 2 42010823 3 42010824 4 42010825 5 42010826 6 42010827 7 42010829 3,5 **ACS® LD MB tibial component cementless pc** 42010902 2 42010903 3 42010904 4 42010905 5 42010906 6 42010907 7 42010909 3,5 **ACS® MB SC tibial component cementless pc** 42014102 2 42014103 3 42014104 4 42014105 5 42014106 6 **ACS® MB SC tibial component cemented** 42014002 2 42014003 3 42014004 4 42014005 5 42014006 6 **ACS® FB tibial component cemented** 42010422 2 left 42010423 3 left 42010424 4 left 42010425 5 left 42010426 6 left 42010429 3,5 left 42010432 2 right 42010433 3		

			right 42010434 4 right 42010435 5 right 42010436 6 right 42010439 3,5 right **ACS® FB tibial component cementless, pc** 42010402 2 left 42010403 3 left 42010404 4 left 42010405 5 left 42010406 6 left 42010409 3.5 left 42010412 2 right 42010413 3 right 42010414 4 right 42010415 5 right 42010416 6 right 42010419 3.5 right **ACS® LD FB tibial component cemented** 42011002 2 left 42011003 3 left 42011009 3.5 left 42011004 4 left 42011005 5 left 42011006 6 left 42011012 2		

			right 42011013 3 right 42011019 3.5 right 42011014 4 right 42011015 5 right 42011016 6 right **ACS® LD FB tibial component cementless** 42010442 2 left 42010443 3 left 42010449 3.5 left 42010444 4 left 42010445 5 left 42010446 6 left 42010452 2 right 42010453 3 right 42010459 3.5 right 42010454 4 right 42010455 5 right 42010456 6 right **ACS® MB SC tibial spacer ll-rm** 42085052 2/5mm 42085053 3/5mm 42085054 4/5mm 42085055 5/5mm 42085056 6/5mm 42085102		

			2/10mm 42085103 3/10mm 42085104 4/10mm 42085105 5/10mm 42085106 6/10mm **ACS® MB SC tibial spacer rl-lm** 42080052 2/5mm 42080053 3/5mm 42080054 4/5mm 42080055 5/5mm 42080056 6/5mm 42080102 2/10mm 42080103 3/10mm 42080104 4/10mm 42080105 5/10mm 42080106 6/10mm **ACS® FB tibial spacer medial** 42070052 2/5mm 42070053 3/5mm 42070054 4/5mm 42070055 5/5mm 42070056 6/5mm 42070059 3,5/5mm 42070102 2/10mm 42070103 3/10mm 42070104 4/10mm 42070105		

			5/10mm 42070106 6/10mm 42070109 3,5/10mm **ACS® FB tibial spacer lateral** 42075052 2/5mm 42075053 3/5mm 42075054 4/5mm 42075055 5/5mm 42075056 6/5mm 42075059 3,5/5mm 42075102 2/10mm 42075103 3/10mm 42075104 4/10mm 42075105 5/10mm 42075106 6/10mm 42075109 3,5/10mm **ACS® extension stem** 42014025 14/25mm 42014050 14/50mm 42014075 14/75mm **ACS® extension stem male taper** 42014225 14/25mm 42014235 14/35mm 42014250 14/50mm **ACS® LD extension stem male taper** 42004225 14/25mm		

			42004235 14/35mm 42004250 14/50mm **ACS® stem** 42081210 12*100mm 42081410 14*100mm 42081610 16*100mm 42081810 18*100mm 42082010 20*100mm 42082210 22*100mm 42081215 12*150mm 42081415 14*150mm 42081615 16*150mm 42081815 18*150mm 42082015 20*150mm 42082215 22*150mm 42081220 12*200mm 42081420 14*200mm 42081620 16*200mm 42081820 18*200mm **ACS® stem cementless HA** 42091210 12*100mm 42091410 14*100mm 42091610 16*100mm 42091810 18*100mm 42092010 20*100mm 42092210 22*100mm 42091215		

			12*150mm 42091415 14*150mm 42091615 16*150mm 42091815 18*150mm 42092015 20*150mm 42092215 22*150mm 42091220 12*200mm 42091420 14*200mm 42091620 16*200mm 42091820 18*200mm **ACS® MB off set adapter** 42083002 2mm 42083004 4mm **ACS® double taper** 42010460 0mm 42010462 +2mm 42010464 +4mm 42010466 +6mm **ACS® MB PS PE- insert hyperflex** 42028210 2; 10mm 42028212 2; 12.5mm 42028215 2; 15mm 42028217 2; 17.5mm 42028220 2; 20mm 42028310 3; 10mm 42028312 3; 12.5mm 42028315 3; 15mm 42028317 3; 17.5mm 42028320 3;		

			20mm 42028410 4; 10mm 42028412 4; 12.5mm 42018415 4; 15mm 42028417 4; 17.5mm 42028420 4; 20mm 42028510 5; 10mm 42028512 5; 12.5mm 42028515 5; 15mm 42028517 5; 17.5mm 42028520 5; 20mm 42028610 6; 10mm 42028612 6; 12.5mm 42028615 6; 15mm 42028617 6; 17.5mm 42028620 6; 20mm **ACS® MB SC PE- insert hyperflex** 42029210 2; 10mm 42029212 2; 12.5mm 42029215 2; 15mm 42029217 2; 17.5mm 42029220 2; 20mm 42029310 3; 10mm 42029312 3; 12.5mm 42029315 3; 15mm 42029317 3; 17.5mm		

			42029320 3; 20mm 42029410 4; 10mm 42029412 4; 12.5mm 42029415 4; 15mm 42029417 4; 17.5mm 42029420 4; 20mm 42029510 5; 10mm 42029512 5; 12.5mm 42029515 5; 15mm 42029517 5; 17.5mm 42029520 5; 20mm 42029610 6; 10mm 42029612 6; 12.5mm 42029615 6; 15mm 42029617 6; 17.5mm 42029620 6; 20mm **ACS® FB PS PE-insert hyperflex** 42401210 2; 10mm 42401212 2; 12.5mm 42401215 2; 15mm 42401217 2; 17.5mm 42401220 2; 20mm 42401310 3; 10mm 42401312 3; 12.5mm 42401315 3; 15mm 42401317 3; 17.5mm		

			42401320 3; 20mm 42401410 4; 10mm 42401412 4; 12.5mm 42401415 4; 15mm 42401417 4; 17.5mm 42401420 4; 20mm 42401510 5; 10mm 42401512 5; 12.5mm 42401515 5; 15mm 42401517 5; 17.5mm 42401520 5; 20mm 42401610 6; 10mm 42401612 6; 12.5mm 42401615 6; 15mm 42401617 6; 17.5mm 42401620 6; 20mm **ACS® FB SC PE- insert hyperflex** 42403210 2; 10mm 42403212 2; 12.5mm 42403215 2; 15mm 42403217 2; 17.5mm 42403220 2; 20mm 42403310 3; 10mm 42403312 3; 12.5mm 42403315 3; 15mm 42403317 3;		

			17.5mm 42403320 3; 20mm 42403410 4; 10mm 42403412 4; 12.5mm 42403415 4; 15mm 42403417 4; 17.5mm 42403420 4; 20mm 42403510 5; 10mm 42403512 5; 12.5mm 42403515 5; 15mm 42403517 5; 17.5mm 42403520 5; 20mm 42403610 6; 10mm 42403612 6; 12.5mm 42403615 6; 15mm 42403617 6; 17.5mm 42403620 6; 20mm **ACS® FB PE-insert implacross® E** 42050210 2; 10mm 42050212 2; 12.5mm 42050215 2; 15mm 42050217 2; 17.5mm 42050220 2; 20mm 42050310 3; 10mm 42050312 3; 12.5mm 42050315 3; 15mm		

			42050317 3; 17.5mm 42050320 3; 20mm 42050410 4; 10mm 42050412 4; 12.5mm 42050415 4; 15mm 42050417 4; 17.5mm 42050420 4; 20mm 42050510 5; 10mm 42050512 5; 12.5mm 42050515 5; 15mm 42050517 5; 17.5mm 42050520 5; 20mm 42050610 6; 10mm 42050612 6; 12.5mm 42050615 6; 15mm 42050617 6; 17.5mm 42050620 6; 20mm **ACS® FB PS PE-insert hyperflex implacross® E** 42053210 2; 10mm 42053212 2; 12.5mm 42053215 2; 15mm 42053217 2; 17.5mm 42053220 2; 20mm 42053310 3; 10mm 42053312 3; 12.5mm 42053315 3;		

			15mm 42053317 3; 17.5mm 42053320 3; 20mm 42053410 4; 10mm 42053412 4; 12.5mm 42053415 4; 15mm 42053417 4; 17.5mm 42053420 4; 20mm 42053510 5; 10mm 42053512 5; 12.5mm 42053515 5; 15mm 42053517 5; 17.5mm 42053520 5; 20mm 42053610 6; 10mm 42053612 6; 12.5mm 42053615 6; 15mm 42053617 6; 17.5mm 42053620 6; 20mm **ACS® FB SC PE- insert hyperflex implacross® E** 42055210 2; 10mm 42055212 2; 12.5mm 42055215 2; 15mm 42055217 2; 17.5mm 42055220 2; 20mm 42055310 3; 10mm 42055312 3;		

			12.5mm 42055315 3; 15mm 42055317 3; 17.5mm 42055320 3; 20mm 42055410 4; 10mm 42055412 4; 12.5mm 42055415 4; 15mm 42055417 4; 17.5mm 42055420 4; 20mm 42055510 5; 10mm 42055512 5; 12.5mm 42055515 5; 15mm 42055517 5; 17.5mm 42055520 5; 20mm 42055610 6; 10mm 42055612 6; 12.5mm 42055615 6; 15mm 42055617 6; 17.5mm 42055620 6; 20mm **ACS® PE-patella cemented** 42030326 26mm 42030329 29mm 42030332 32mm 42030335 35mm **EPORE ® metaphyseal component tibial for ACS ®FB** 42075112 2 42075113 3 42075114 4 42075115 5 **EPORE ®**		

			metaphyseal component femoral for ACS ®SC 42075122 2 42075123 3 42075124 4 42075125 5 Shelf Life: 05 years Fee submitted: Rs. 50,000/-		
173	M/s Al Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. (ELI-00285) **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Suzhou Colour-way Enterprise Development Co., Ltd. Dongqiao Industrial Area, Xiangcheng District, Suzhou. Manufacturing site: Longsha industrial park, Huashi Town, Jiangyin (FSC China valid till 03-01-2020)	Surgitex® Latex Surgical Gloves (Powdered) Class B Sizes 6, 6.5, 7, 7.5, 8, 8.5 Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Sterile, single use latex rubber surgical gloves	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
174	M/s. Curative Pharmaceuticals (Pvt) Ltd., 500, 5th Floor, Plaza No. 54, Block B, Civic Centre, Phase-IV, Bahria Town, Rawalpindi / Islamabad. ELI-00330 **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. LifeScience Plus Inc., 2520-A Wyandotte St., Mountain View, CA, 94043, USA. **Contract Manufacturer:** M/s. Beijing Takesiman Technology Development Company, Ltd., 5 Li qiao duan, Li Tian Rd, Li Qiao, Beijing, China 101304 FSC USFDA Valid till 17.09.2020	**Blood Stop ®** (Hemostatic Gauze) Class C Sizes and Codes: BS-MP18 --2cm x 2cm BS-09--1"x 1" (2.5cm x 2.5cm) BS-10--2"x 2" (5cm x 5cm) BS-11--2"x 4" (5cm x 10cm) BS-12--4"x 4" (10cm x 10cm) BS-13--4"x 8" (10cm x 20cm) BS-OTC-28--1"x 1" (2.5cm x 2.5cm) 2" x 2"(5.0cm x	Sterile, external, short term use hemostatic dressing for the control of bleeding from lacerations, cuts, abrasions and venipuncture for the general population and for those on anticoagulant medications etc	**Approved.**

			5.0cm) Shelf Life: 05 years Fee submitted: Rs. 50,000/-		
175	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. LifeScience Plus Inc., 2520-A Wyandotte St., Mountain View, CA, 94043, USA. **Contract Manufacturer:** M/s. Beijing Takesiman Technology Development Company, Ltd., 5 Li qiao duan, Li Tian Rd, Li Qiao, Beijing, China 101304 FSC USFDA Valid till 17.09.2020	**Blood Stop ® iX** (Absorbent hemostat for hospital use) Class C Sizes and Codes: BS-iX14-------- 2"x2" (5cm x 5cm) BS-iX27-------- 0.5"x2" (1.3cm x 5cm) BS-iX15-------- 2"x4" (5cm x 10cm) BS-iX17-------- 4"x8" (10cm x 20cm) BS-iX20-------- 2"x14" (5cm x 35cm) BM-iX24------- 3"x24" (7.5cm x 61cm) Shelf Life: 05 years Fee submitted: Rs. 50,000/-	Sterile, internal use wholly absorbable for the control of bleeding during and after surgery for the general population and for those on anticoagulant medications.	**Approved.**
176	M/s. Ferozsons LaboratoriesLimited, P.O Ferozsons, Amangarh, Nowshera (KPK). (ELI-00120) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** M/s. Boston Scientific Corporation, 780 Brookside Drive Spenser, USA 47460 FSC US FDA valid till 05-08-2020	**LeVeen™ SuperSlim™ Needle Electrode System** Class C Codes: M001262260 LeVeen SuperSlim Needle Electrode 2.0cm x 15cm M001262270 LeVeen SuperSlim Needle Electrode 2.0cm x 25cm M001262280 LeVeen	Intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.	**Approved.**

			SuperSlim Needle Electrode 3.0cm x 15cm M001262290 LeVeen SuperSlim Needle Electrode 3.0cm x 25cm Shelf life: 36 Months Fee Submitted: Rs: 50,000/-.		
177	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Limited Business and Technology Park, Model Farm Road, Cork, Ireland. FSC Ireland valid till 04-09-2023	Occlusion Balloon Catheter Class C Codes: M001171020 OB/7/2/65 standard M001171030 OB/7/2/100 standard M001173010 OB/6-6/2/80 Berenstein Shelf Life: 18 Months Fee Submitted: Rs: 50,000/-	Indicated for temporary vessel occlusion in application including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.	**Approved.**
178	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica FSC Ireland valid till 10-11-2020	IntellaNAV Open-Irrigated Ablation Catheter Class D Codes: M004EPTR96200 (Standard Curve) M004EPTR9620K20 (Large Curve) M004EPTR9620N40 (Asymmertic Curve) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	Is indicated for use in patient who require catheter-based cardiac electrophysiological mapping (stimulating and recording) and when used in conjuction with a radiofrequency generator, for cardic ablation.	**Approved.**
179	-do- **Evaluator:**	**Legal Manufacturer:** Boston Scientific Corporation	Straight-18 Fibered Platinum Coil	Non-neurovascular embolization	**Approved.**

	Ms. Unum Zia Shamsi	300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Limited Business and Technology Park, Model Farm Road, Cork, Ireland. FSC Ireland valid till 23-03-2022	Class C Code: M0013120020 2mm Straight-18 (Bx/1) M0013120021 2mm Straight-18 (Bx/5) M0013120050 5mm Straight-18 (Bx/1) M0013120051 5mm Straight-18 (Bx/5) Shelf Life: 36 months Fee submitted: Rs. 50,000/-	coil intended for arterial and venous embolizations in the peripheral vasculature.	
180	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica FSC Ireland valid till 10-11-2020	Blazer Dx-20 Bidirectional Steerable Diagnostic Catheter Class D Codes: UPN: M00420SL2520 GTIN: 08714729780502 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-5-2mm UPN: M00420SL2820 GTIN:08714729780519 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-8-2mm UPN: M00420SL2220 GTIN:	Designed for use in intracardiac pacing and recording	**Approved.**

			08714729780489 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-2-2mm UPN: M00420SL5550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/5-5-5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-8-2-8-2-8-2-8-2-60-2-8-2-8-2-8-2-8-2mm UPN:M00420SL220250 GTIN: 08714729780540 Bidirectional		

			Steerable Diagnostic Catheter (Duodecapolar/Super Large Curve) 7F(2.33mm)/2-20-2-2-2-2-2-2-2-2-2-2-25-2-25-2-25-2mm UPN: M00420M2520 GTIN: 08714729780564 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/2-5-2mm UPN: M00420M2220 GTIN: 08714729780557 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/2-2-2mm UPN: M00420M255050 GTIN: 08714729780571 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/2-5-2-5-2-5-2-5-2-50-5-5-5-5-5-5-5-5-5mm UPN: M00420M270280 GTIN: 08714729780588 Bidirectional		

			Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/2-2-2-2-2-2-2-2-2-70-2-8-2-8-2-8-2-8-2mm UPN: M00420M54050 GTIN: 08714729780595 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/5-5-5-5-5-5-5-5-5-40-5-5-5-5-5-5-5-5-5-5mm UPN: M00420M28400 GTIN: 08714729780601 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/Medium/Duodecapolar/2-8-2-8-2-8-2-8-2-40-2-8-2-8-2-8-2-8-2-8-2mm UPN: M00420M210350 GTIN: 08714729780618 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/ Medium Curve) 7F(2.33mm)/2-10-2-10-2-10-2-10-2-10-2-35-2-10-2-10-2-10-2-10-2mm		

			Shelf Life: 3 Years Fee submitted: Rs. 50,000/-		
181	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Limited Business and Technology Park, Model Farm Road, Cork, Ireland. FSC Ireland valid till 12-04-2023	Placehit™ Biliary Wallstent™ (Endoprosthesis for transhepatic use) Class C Codes: H965SCH650700 Wallstent PT 07F 08 050 H965SCH650710 Wallstent PT 07F 08 070 H965SCH650730 Wallstent PT 07F 10 050 H965SCH650740 Wallstent PT 07F 10 070 H965SCH650750 Wallstent PT 07F 10 090 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	To be used to help maintain bile duct patency in the following patient candidates: a) Patients presenting pancreatic carcinoma which is compressing the biliary tree. b) Patients presenting cholangiocarcinoma which has led to biliary obstruction. c) Patients presenting an extra-hepatic biliary obstruction due to gallbladder carcinoma, metastases, or ampullary carcinoma. Any use other than that indicated is not recomended.	**Approved.**
182	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa	**IntellaTip MiFi XP Temperature Ablation Catheter** Class D Codes: M004EPM45000 (Standard Curve) 8mm x 8F M004EPM4500K 20 (Large Curve)	Therapeutic, temperature-controlled, cardiac ablation catheters designed for use in intracardiac ablation, mapping and pacing	**Approved.**

		Rica FSC Ireland valid till 10-11-2020	8mm x 8F M004EPM4500N 40 (Asymmetric Curve) 8mm x 8F M004EPM47900 08714729858874 (Standard Curve) 10mm x 8F M004EPM4790K 20 (Large Curve) 10mm x 8F M004EPM4790N 40 (Asymmetric Curve) 10mm x 8F Shelf Life: 36 months Fee Submitted: Rs: 50,000/-		
183	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation Two Scimed Place, Maple Grove, MN USA 55311 (FSC US FDA expired on 26-06-2019)	AngioJet™ ZelanteDVT™ Over the wire Thrombectomy Set Class C Codes: 114610-001 08714729904724 AngioJet™ ZelanteDVT™ Over-The-Wire Thrombectomy Set 114610-002 08714729904731 AngioJet™ ZelanteDVT™ Over-The-Wire Thrombectomy Set Shelf life: 24 Months Fee Submitted: Rs: 50,000/-	Intended for use with the AngioJet Ultra Console to break apart and remove thombus in peripheral vasculature. Also intended for use with the AngioJet Ultra Power Pulse™ technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. Not to be used in treatment of pulmonary	**Approved**subject to provision of valid Free Sale Certificate duly attested by Embassy of Pakistan.

				embolism, and in coronary or cerebral or carotid vasculature	
184	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way, Marlborough, MA (01752) USA Manufacturing site: FMD, Co., Ltd 1-166 Shimoobari Nakashima Komaki, Aichi, Japan, 485-0051. FSC US FDA valid till 26-03-2021	Marvel ™ Guidewire Class D Codes: H749393011902 08714729881179 Marvel Guidewire 190cm, Straight-tip H749393013002 08714729881193 Marvel Guidewire 300cm, Straight-tip H74939301190J2 08714729881186 Marvel Guidewire 190cm, J-tip- H74939301300J2 08714729881209 Marvel Guidewire 300cm, J-tip Shelf life: 3 years Fee submitted: Rs. 50,000/-	Intended to facilitate the placement of balloon dilatation catheters or other interventional therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or other intravascular interventinal procedures. These guidewires are not intended for use in the cerebral vasculature.	**Approved.**
185	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA	AngioJet™ Spiroflex™ Monorail™ Thrombectomy Set	Intended for use in breaking apart and removing thrombus from infra-inguinal	**Approved.**

		Manufacturing Site: Boston Scientific Corporation Two Scimed Place, Maple Grove, MN USA 55311 (FSC Ireland valid till 05-03-2023)	Class D Codes: 106553-002 106553-003 106553-004 106553-005 106553-006 106553-007 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	peripheral arteries. Not to be used for treatment of pulmonary embolism and in carotid/cerebral vasculature, coronary vasculature.	
186	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing site: Boston Scientific Corporation, 302 Parkway, Global Park La Aurora, Heredia, Costa Rica. (FSC US FDA valid till 05-08-2020)	ChoICE™ Magnet Guidewire with ICE™ Hydrophilic Coating Class D Codes: H7491213201M2 08714729877103 0.014", 182cm, Straight, 5pk H7491213201MJ2 08714729877110 0.014", 182cm, J Tip, 5pk H7491213501M2 08714729877165 0.014", 182cm, Straight, 5pk H7491213501MJ2 08714729877172 0.014", 182cm, J Tip, 5pk H7491213301M2 08714729877127	Intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. Not intended for use in the cerebral vasculature.	**Approved.**

			0.014", 182cm, Straight, 5pk H7491213301MJ 2 08714729877134 0.014", 182cm, J Tip, 5pk H7491213401M2 08714729877141 0.014", 182cm, Straight, 5pk H7491213401MJ 2 08714729877158 0.014", 182cm, J Tip, 5pk Shelf life: 24 Months		
187	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site: Boston Scientific Corporation, 302 Parkway, Global Park Heredia, Costa Rica. (FSC Ireland valid till 10-11-2020)	Polaris X™ Unidirectional Steerable Diagnostic Catheter Class D Codes: M0047000D0 08714729270133 Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/2.5MM /105CM) M0047001D0 08714729270140 Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/5MM/105CM) M0047003D0 08714729270164	Intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and /or recording of electrical potentials.	**Approved.**

			Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/2.5/5/2 .5MM/105CM) M0047004D0 08714729270171 Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/2-8-2MM/105CM) M0047005D0 08714729270188 Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/2-10-2MM/105CM) Shelf Life: 2 Years Fee submitted: Rs. 50,000/-		
188	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site: Boston Scientific Corporation, 302 Parkway, Global Park Heredia, Costa Rica. (FSC Ireland valid till 10-11-2020)	Blazer II XP Temperature Ablation Catheter Class D Codes: M004EPT4500T HK20 08714729268406 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4500T HN40 08714729268437 Temperature Ablation Catheter (Asymmetric N4 Curve/Std Distal)	Therapeutic, temperature-controlled, cardiac ablation catheters designed for use in intracardiac ablation, mapping and pacing. Delivers power upto 150W.	**Approved.**

			M004EPT4500TH0 08714729268390 Temperature Ablation Catheter (Standard Curve/Std Distal) M004EPT4500THM0 08714729268413 Temperature Ablation Catheter (Standard Curve/Med Distal) M004EPT4500THMK20 08714729268420 Temperature Ablation Catheter (Large Curve/Med Distal) M004EPT4790TH0 08714729268444 Temperature Ablation Catheter (Standard Curve/Std Distal) M004EPT4500T0 08714729335313 Temperature Ablation Catheter (Standard Curve/Std Distal) M004EPT4500TK20 08714729335337 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4500TN40 08714729335382 Temperature Ablation Catheter (Asymmetric N4 Curve/Std Distal)		

			M004EPT4500T MK20 08714729335368 Temperature Ablation Catheter (Large Curve/Med Distal) M004EPT4790T K20 08714729335498 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4790T HK20 08714729268451 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4790T HM0 08714729268468 Temperature Ablation Catheter (Standard Curve/Med Distal) M004EPT4790T HMK20 08714729268475 Temperature Ablation Catheter (Large Curve/Med Distal) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-		
189	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park,	**Blazer Prime XP Temperature Ablation Cathether** **(Codes & Sizes As per FSC)** Class D Shelf Life: 36 Months	Blazer Ablation Catheter are intended to be used as a part of Boston Scientific Corporation's Cardiac Ablation	**Approved** subject to provision of updated Letter of Authorization.

		Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	Rs.50,000/-	Systems. The Commercially released system is indicated for interruption of accessory artioventricular conduction pathways associated with Tachycardia.	
190	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	**Blazer II HTD Temperature Ablation Catheter (Codes & Sizes As per FSC)** Class D Shelf Life: 36 Months Rs.50,000/-	The Boston Scientific Cardiac Ablation systems is indicated for use for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia.	**Approved** subject to provision of updated Letter of Authorization.
191	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park,	**Blazer Prime HTD Temperature Ablation Cathether** **UPN:M004EPTP5031TH0** **GTIN: 08714729786320**	Blazer Prime Catheters are intended to be used as a part of Boston Scientific Corporation's Cardiac Ablation System. The	**Approved** subject to provision of updated Letter of Authorization.

		Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	**Temperature ablation Catheter (Standard Curve).** **UPN:M004EPTP5031THK20 GTIN:08714729786337 Temperature ablation Catheter (Large Curve).** **UPN:M004EPTP5031THN40 GTIN:08714729786344 Temperature ablation Catheter (Asymmetric Curve).** Class D Shelf Life: 36 Months Rs.50,000/-	commercially released system is indicated for interruption of accessory atrioventricular Conduction pathways associated with tachycardia, ventricular Tachycardia, atrial Flutter, atrial tachycardia and for creation of complete Av block in patients with rapid ventricular response to an atrial arrhythmia-typically chronic, drug refactory atrial fibrillation.	
192	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	**Blazer II Temperature Ablation Catheter (Codes & Sizes As per FSC)** Class D Shelf Life: 36 Months Rs.50,000/-	The Boston Scientific Cardiac Ablation Systems is indicated for use for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of Av nodal reentranttac;ycardia and for creation of completer Av	**Approved** subject to provision of updated Letter of Authorization.

				block in patient with a rapid ventricular response to an atrial arrhythmia-typically chronic, drug refactory atrial fabrillation.	
193	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	**Blazer Open-Irrigated Ablation Catheter** UPN: M004EPT96200 GTIN: 08714729792925 Ablation Catheter (Standard Curve) UPN:M004EPT9620K20 GTIN:08714729792932 Ablation Catheter (Large Curve) UPN:M004EPT9620N40 GTIN:08714729792956 Ablation Catheter (Asymemetric Curve) UPN:M004EPT9620K2E0 GTIN:08714729792963 Ablation Catheter (Large Curve/ Extra Long) Class D Shelf Life: 36 Months Rs.50,000/-	Blazer Open-Irrigated Ablation Catheter is indicated for use in catheter –based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.	**Approved** subject to provision of updated Letter of Authorization.
194	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:**	**Radia Bidirectional Steerable Diagnostic Catheter (Codes & Sizes As per FSC)**	The Steerable diagnostic electrode catheter is intended for temporary intracardiac	**Approved** subject to provision of updated Letter of Authorization.

		Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 26-05-2021	Class D Shelf Life: 3 Years Rs.50,000/-	sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.	
195	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 26-05-2021	**Orbiter ST Bidirectional Steerable Diagnostic Catheter (Codes & Sizes As per FSC)** Class D Shelf Life: 3 Years Rs.50,000/-	The Steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.	**Approved** subject to provision of updated Letter of Authorization.
196	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 26-05-2021	**Dynamic XT Unidirectional Steerable Diagnostic Catheter Codes & Sizes As per FSC** Class D Shelf Life: 3 Years Rs.50,000/-	The Steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.	**Approved** subject to provision of updated Letter of Authorization.
197	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 26-05-2021	**Dynamic Tip Unidirectional Steerable Diagnostic Catheter Codes & Sizes As per FSC** Class D Shelf Life: 3 Years Rs.50,000/-	The Steerable diagnostic electrode catheters are intended for temporary intra cardiac sensing, recording, stimulation and temporary pacing during the evaluation	**Approved** subject to provision of updated Letter of Authorization.

				of cardiac arrhythmias.	
198	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, Costa Rica. FSC Ireland Valid till 26-05-2021	**EP XT Unidirectional Steerable Diagnostic Catheter Codes & Sizes As per FSC** Class D Shelf Life: 3 Years Rs.50,000/-	The Steerable diagnostic electrode catheters are intended for temporary intra cardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.	**Approved** subject to provision of updated Letter of Authorization.
199	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Limited, Business and Technology Park, Model Farm Road, Cork., Ireland. FSC Ireland Valid till 04-09-2023	MAMBA™ Microcatheter **MAMBA™ MicroCatheter MAMBA 135 cm (OUS) H7493928713520** Class D Shelf Life: 2 Years Rs.50,000/-	Peripheral /coronary vascular microcatheter	**Approved** subject to provision of updated Letter of Authorization.
200	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland. FSC Ireland Valid till 12-04-2023	**Wallstent™ RP Endoprothesis Self-Expanding Stent (Codes & Sizes per FSC)** Class C Shelf Life: 24 Months Rs.50,000/-	The Wallstent RP Endoprosthesis Self-Expanding Stent is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of commmon and or external iliac artery stenotic lesions which are 10 cm in length	**Approved** as class-D medical devicesubject to provision of updated Letter of Authorization.
201	-do-	**Legal Manufacturer:** Boston Scientific	**Direxion™ Torqueable**	The Direxionand	**Approved** subject to provision of

	Evaluator: Shahid Muhammad Iqbal	Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Limited, Business and Technology Park, Model Farm Road, Cork, Ireland. FSC Ireland Valid till 23-03-2022	**Microcatheter (Codes & Sizes per FSC)** Class C Shelf Life: 24 Months Rs.50,000/-	Direxion Torqueable Microcatheters are intended for peripheral vascular use. The preloaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculatre.	updated Letter of Authorization.
202	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation 2546 First Street, Propark EL Coyol, Alajuela COSTA RICA 20904 FSC USA Valid till 19-12-2019	**Plantinum Plus™ Guidewires** Class B Shelf Life: 36 Months Codes & Sizes as per FSC Rs.50,000/-	Peripheral Vascular Guidewire The Platinum Plus Guidewire facilitates placement of a catheter during diagnostic or interventional intravascular procedures.	**Approved** subject to provision of updated Letter of Authorization.
203	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland. FSC Ireland Valid till 12-04-2023	**WATCHMAN™ Access System** Cardiac Occluder Delivery Kit: Access System **M635TS10060 WATCHMAN Access Sys-ST Single Curve, 14F M635TS20060 WATCHMAN Access Sys-ST Double Curve, 14F M635TS40060 WATCHMAN Access Sys-ST Anterior Curve,**	The WATCHMAN Access System is intended to provide vascular and transseptal access for the WATCHMAN Left atrial Appendage Closure device with delivery system.	**Approved** subject to provision of updated Letter of Authorization.

			14F Class D Shelf life: 36 Months Rs.50,000/-		
204	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland. FSC Ireland Valid till 12-04-2023	**WATCHMAN™ Left Artial Appendage Closure Device with Delivery System** **M635WS21060 21mm WATCHMAN LAA Closure/Delivery, 12F** **M635WS24060 24mm WATCHMAN LAA Closure/Delivery, 12F** **M635WS27060 27mm WATCHMAN LAA Closure/Delivery, 12F** **M635WS30060 30mm WATCHMAN LAA Closure/Delivery, 12F** **M635WS33060 33mm WATCHMAN LAA Closure/Delivery, 12F** Class D Shelf life: 36 Months Rs.50,000/-	The Watchman LAA closure Technology is intended to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for anticoagulation therapy or who have a contraindication to anticoagulation therapy.	**Approved** subject to provision of updated Letter of Authorization.
205	-do- **Evaluator:** Shahid Muhammad	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA.	**ELUVIA™ Over-The-Wire Drug-Eluting Vascular Stent System**	The ELUVIA Drug Eluting Vascular Stent System is intended to	**Approved** subject to provision of updated Letter of Authorization.

	Iqbal	01752 USA. **Manufacturing Site:** Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311 USA. Boston Scientific Limited , Ballybrit Business Park, Galway, Ireland. FSC Ireland Valid till 05-03-2023 & 12-04-2023	**Codes & Sizes per FSC** Class D Shelf life: 24 Months Rs.50,000/-	improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery with refernce vessel diameter (RVD) ranging from 4.0-6.0 mm	
206	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311 USA. FSC Ireland Valid till 05-03-2023	**Innova™ Over-The-Wire Self – Expanding Stent System (Codes & Sizes per FSC)** Class C Shelf life: 36 Months Rs.50,000/-	The Innova Stent System is indicated for the treatment of peripheral vascular lesion.	**Approved** subject to provision of updated Letter of Authorization.
207	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. **Manufacturing Site:** M/s. Boston Scientific Corporation, 780 Brookside Drive Spenser, USA 47460 FSC USFDA Valid till 05-08-2020	**LeVeen™ CoAccess™ Needle Electrode System** **M001262220 08714729454922** **LeVeen CoAccess Electrode System 3.0cm x 15cm** **M001262230 08714729295617** **LeVeen CoAccess Electrode System 3.5cm x 15cm** **M001262240 08714729454939**	The LeVeen Needle Electrode Family / Soloist Single Needle Electrode is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including	**Approved** subject to provision of updated Letter of Authorization.

			LeVeen CoAccess Electrode System 4.0cm x 15cm Class C Shelf life: 36 Months Rs.50,000/-	partial or complete ablation of nonres ectable liver lesions.	
208	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, boston scientific Way, Marlborough, MA (01752) USA **Manufacturing Site:** FMD, Co., Ltd 1-166 Shimoobari Nakashima Komaki Aichi Japan 485-0051. FSC USA Valid till 26th March , 2021	**Hornet ™ Guidewire H749393051902 08714729886655 Hornet Guidewire 190cm, Straight-tip H749393053002 08714729886662 Hornet Guidewire 300cm, Straight-tip** Class D Shelf life: 3years Rs.50,000/-	Boston Scientific Hornet, Hornet 10 and Hoenet 14 Guidewires are intended to facilitate the placement of balloon dilatation chatheters or other interventional therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or other intravascular interventional procedures. These guidewires are not intended for use in the cerebral vasculature.	**Approved** subject to provision of updated Letter of Authorization.
209	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, boston scientific Way, Marlborough, MA (01752) USA **Manufacturing Site:** FMD, Co., Ltd 1-166 Shimoobari Nakashima Komaki Aichi Japan 485-0051.	**Fighter ™ Guidewire** **H749393031902 08714729886617 Fighter Guidewire 190cm, Straight-tip H749393033002 08714729886624 Fighter Guidewire**	Boston scientific Fighter ™ , Marvel ™ , Samurai ™ and Samurai ™ Rc Duidewires are intended to facilitate the placement of balloon dilatation	**Approved** subject to provision of updated Letter of Authorization.

		FSC USA Valid till 26th March , 2021	**300cm, Straight-tip** Class D Shelf life: 3years Rs.50,000/-	catherters or other interventional therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or other intravascular interventinal procedures. These guidewires are not intended for use in the cerebral vasculature.	
210	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA (01752) USA **Manufacturing Site:** Boston Scientific Limited , Ballybrit Business Park, Galway, Ireland. FSC Ireland Valid till 4thJanuary,2023	**Wolverine ™ Coronary Cutting Balloon ™ MONORAIL ™ Microsurgical Dilatation Device** **H74939403062000Wolverine Cutting Balloon MR, OUS 6mmx2.0mm** **H74939403062250Wolverine Cutting Balloon MR, OUS 6mmx2.25mm** **H74939403062500 Wolverine Cutting Balloon MR, OUS 6mmx2.50mm** **H74939403062750Wolverine Cutting Balloon MR, OUS 6mmx2.75mm** **H74939403063000Wolverine Cutting Balloon MR, OUS 6mmx3.00mm**	The Wolverine Cuting Balloon device is indicated for use in patients with coronary vessel diseases who are acceptable candidates for coronary artery bypass graft surgery, should it be urgently needed, for the purpose of improving myocardial perfusion.	**Approved** subject to provision of updated Letter of Authorization.

			H7493940306325 0Wolverine Cutting Balloon MR, OUS 6mmx3.25mm H7493940306350 0Wolverine Cutting Balloon MR, OUS 6mmx3.5mm H7493940306375 0Wolverine Cutting Balloon MR, OUS 6mmx3.75mm H7493940306400 0Wolverine Cutting Balloon MR, OUS 6mmx4.00mm **H7493940310200 0Wolverine Cutting Balloon MR, OUS 10mmx2.00mm H7493940310225 0Wolverine Cutting Balloon MR, OUS 10mmx2.25mm H7493940310250 0Wolverine Cutting Balloon MR, OUS 10mmx2.50mm H7493940310275 0Wolverine Cutting Balloon MR, OUS 10mmx2.75mm H7493940310300 0Wolverine Cutting Balloon MR, OUS 10mmx3.00mm H7493940310325 0Wolverine Cutting Balloon MR, OUS 10mmx3.25mm**		

			H7493940310350 0Wolverine Cutting Balloon MR, OUS 10mmx3.50mm H7493940310375 0Wolverine Cutting Balloon MR, OUS 10mmx3.75mm H7493940310400 0Wolverine Cutting Balloon MR, OUS 10mmx4.00mm **H7493940315200 0Wolverine Cutting Balloon MR, OUS 15mmx2.00mm H7493940315225 0Wolverine Cutting Balloon MR, OUS 15mmx2.25mm H7493940315250 0Wolverine Cutting Balloon MR, OUS 15mmx2.50mm H7493940315275 0Wolverine Cutting Balloon MR, OUS 15mmx2.75mm H7493940315300 0Wolverine Cutting Balloon MR, OUS 15mmx3.00mm H7493940315325 0Wolverine Cutting Balloon MR, OUS 15mmx3.25mm H7493940315350 0Wolverine Cutting Balloon MR, OUS 15mmx3.50mm**		

			H7493940315375 0Wolverine Cutting Balloon MR, OUS 15mmx3.75mm H7493940315400 0Wolverine Cutting Balloon MR, OUS 15mmx4.00mm Class D Shelf life: 2years Rs.50,000/-		
211	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Boston Scientific Corporation 300, boston scientific Way, Marlborough, MA (01752) USA **Manufacturing Site:** FMD, Co., Ltd 1-166 Shimoobari Nakashima Komaki Aichi Japan 485-0051. FSC USA Valid till 26th March , 2021	SAMAURAI ™ Guidewire **H749393021902 08714729881216 Samurai Guidewire 190cm, Straight-tip H749393023002 08714729881230 Samurai Guidewire 300cm, Straight-tip H74939302190J2 08714729881223 Samurai Guidewire 190cm, J-tip H74939302300J2 08714729881247 Samurai Guidewire 300cm, J-tip** Class D Shelf life: 3 years Rs.50,000/-	Catheter Guidewire	**Approved** subject to provision of updated Letter of Authorization.
212	M/s. Global Marketing Services. 111, Hali Road Westridge1, Rawalpindi ELI-00109 **<u>Evaluator</u>:** Ms. Unum Zia	Legal Manufacturer: Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site: Boston Scientific Corporation, 302	Blazer II XP Temperature Ablation Catheter Class D Codes: M004EPT4500T HK20 08714729268406	Therapeutic, temperature-controlled, cardiac ablation catheters designed for use in intracardiac ablation,	**Approved.**

	Shamsi	Parkway, Global Park Heredia, Costa Rica. (FSC Ireland valid till 10-11-2020)	Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4500T HN40 08714729268437 Temperature Ablation Catheter (Asymmetric N4 Curve/Std Distal) M004EPT4500T H0 08714729268390 Temperature Ablation Catheter (Standard Curve/Std Distal) M004EPT4500T HM0 08714729268413 Temperature Ablation Catheter (Standard Curve/Med Distal) M004EPT4500T HMK20 08714729268420 Temperature Ablation Catheter (Large Curve/Med Distal) M004EPT4790T H0 08714729268444 Temperature Ablation Catheter (Standard Curve/Std Distal) M004EPT4500T0 08714729335313 Temperature Ablation Catheter	mapping and pacing. Delivers power upto 150W.	

			(Standard Curve/Std Distal) M004EPT4500TK20 08714729335337 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4500TN40 08714729335382 Temperature Ablation Catheter (Asymmetric N4 Curve/Std Distal) M004EPT4500TMK20 08714729335368 Temperature Ablation Catheter (Large Curve/Med Distal) M004EPT4790TK20 08714729335498 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4790THK20 08714729268451 Temperature Ablation Catheter (Large Curve/Std Distal) M004EPT4790THM0 08714729268468 Temperature Ablation Catheter (Standard Curve/Med Distal)		

			M004EPT4790T HMK20 08714729268475 Temperature Ablation Catheter (Large Curve/Med Distal) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-		
213	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal manufacturer: Cepheid, 904 Caribbean Drive Sunnyvale CA, 94089, USA Manufacturing site: Cepheid, 904 Caribbean Drive Sunnyvale CA, 94089, USA FSC US FDA valid till 17.12.2020	Xpert® Xpress Flu/RSV Assay kit Class C Xpert® Xpress Flu/RSV Ref No. XPRSFLU/RSV-CE-10 Shelf Life 18 months Fee submitted: Rs. 50,000/-	An automated, multiplex RT-PCR assay intended for the in vitro qualitative detection and differentiation of influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA. Uses nasopharyngeal (NP) swab and nasal swab (NS) specimens.	**Approved.**
214	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. **Manufacturing Site**: BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France issued on 13.12.2017	VIDAS® H. pylori IgG Test Kit Class B Codes: VIDAS® H. pylori IgG Ref. 30192 30 Tests Shelf Life: 11 months Fee submitted: Rs. 25,000/-	An automated qualitative test for use on the instruments of the VIDAS family, for the detection of anti-Helicobacter pylori IgG antibodies in human serum or plasma (EDTA) using the ELFA technique. Used an aid in	**Approved.**

				the diagnosis of H.pylori infection in an adult symptomatic population.	
215	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. Manufacturing Site: BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France issued on 13.12.2017	VIDAS® HAV IgM Test Kit Class C Codes: VIDAS® HAV IgM Ref. 30307 30 Tests Shelf Life: 11 months Fee submitted: Rs. 25,000/-	An automated, qualitative test for use on the VIDAS family instruments for the detection of IgM directed against the hepatitis A virus (HAV) after immunocapture, in human serum or plasma (heparin or EDTA), using the ELFA technique (Enzyme Linked Fluorescent Assay).	**Approved.**
216	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. Manufacturing Site: BioMérieux SA 376 Chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France issued on 20-12-2018	VIDAS® PTH (1-84) Test Kit Class B Codes: VIDAS® PTH (1-84) Ref. 422010 30 Tests Shelf Life: 12 months Fee submitted: Rs. 25,000/-	A third-generation automated quantitative assay for use on the VIDAS family of instruments for the quantitative measurement of the biologically active parathyroid hormone in human serum or plasma using the ELFA (Enzyme Linked	**Approved.**

				Fluorescent Assay) technique.	
217	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: BioMerieux, Inc. 100 Rodolphe Street, Durham, North Carolina, 27712, USA Manufacturing site: BioMerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042 FSC France issued on 25-07-2018	VITEK® 2 AST Cards Class B Codes: **Vitek 2 AST-XN05** Ref No: 413230 Shelf Life: 548 days Contents: SAM, ATM, FEP, CFM, CRO, CXM, C, CS, ESB, LEV, MEM, MNO, MXF, PIP, TE, TCC, TGC, TMP No. of Cards: 20 Cards **Vitek 2 AST-GN81** Ref No: 413438 Shelf Life: 548 days Contents: AN, AMC, AM, CZ, FEP, FOX, CAZ, CRO, CIP, ETP, GM, LEV, MEM, FT, TZP, TE, TM, SXT No. of Cards: 20 Cards **Vitek 2 AST-GN84** Ref No: 413410 Shelf Life: 548 days Contents: AMC, AM, ATM, CZ, FEP, CRO, CIP, ETP, ESB, GM, IPM, LEV, MEM, FT, TZP, TE, SXT	Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to	**Deferred** due to cluster applications.

			No. of Cards: 20 Cards	antimicrobial agents	
			Vitek 2 AST-GP67 Ref No: 22226 Shelf Life: 548 days Contents: AM, P, OXSF, CIP, CM, E, GM, HLG, ICR, LEV, LNZ, MXF. FT, OX1, QDA, RA, HLS, TE, TGC, SXT, VA No. of Cards: 20 Cards	Gram Positive Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents	
			Vitek 2 AST-GP74 Ref No: 414971 Shelf Life: 548 days Contents: AMX, P, CTX, CRO, C, ETP, E, LEV, LNZ, MEM, OFL, TEL, TE, SXT, VA No. of Cards: 20 Cards	Gram Positive Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents	
			Vitek 2 AST-N204 Ref No: 412865 Shelf Life: 548 days Contents: AN, AMC, AM, FEP, CTX, CAZ, CIP, ETP, ESB, FOS, GM, IPM, MEM, FT, NOR, TZP No. of Cards: 20 Cards	Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents	
			Vitek 2 AST-N222 Ref No: 413083 Shelf Life: 548 days	Gram Negative Susceptibility	

			Contents: AN, ATM, FEP, CAZ, CIP, CS, GM, IPM, MEM, MNO, PEF, PIP, TZP, RA, TIC, TCC, TM, SXT No. of Cards: 20 Cards **Vitek 2 AST-N235** Ref No: 413170 Shelf Life: 548 days Contents: AN, AMC, AM, CF, CFM, FOX, CAZ, CRO, CIP, ETP, FOS, GM, NA, FT, NOR, OFL, TZP, TIC, SXT No. of Cards: 20 Cards **Vitek 2 AST-N374** Ref No: 423008 Shelf Life: 548 days Contents: AN, AMC, AM, FEP, CTX, CAZ, CXM, CIP, ETP, ESB, GM, IPM, MEM, TZP, SXT No. of Cards: 20 Cards **Vitek 2 AST-P580** Ref No: 22233 Shelf Life: 548 days Contents: P, OXSF, CM, E, FOS, FA, GM, ICR, LEV, LNZ, MXF, MUP, FT, OX1, RA, TEC, TE, TGC, TM,	Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents. Gram Positive Susceptibility Card intended to determine the susceptibility of	

			SXT, VA No. of Cards: 20 Cards **Vitek 2 AST-P592** Ref No: 22287 Shelf Life: 548 days Contents: AM, P, OXSF, CIP, CM, E, FOS, FA, GM, HLG, IPM, ICR, LNZ, MXF, OX1, RA, HLS, TEC, TE, TGC, SXT, VA No. of Cards: 20 Cards **Vitek 2 AST-YS05** Ref No: 411945 Shelf Life: 548 days Contents: CAS, FLU, VRC No. of Cards: 20 Cards **Vitek 2 AST-YS07** Ref No: 414967 Shelf Life: 548 days Contents: AB, CAS, FLU, FCT, MCF, VRC No. of Cards: 20 Cards **Vitek 2 AST-YS08** Ref No: 420739 Shelf Life: 548 days Contents: AB, CAS, FLU, FCT, MCF, VRC No. of Cards: 20 Cards	Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents. Gram Positive Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents. Fungal Susceptibility Card intended to determine the susceptibility of clinically significant yeasts to antifungal agents Fungal Susceptibility Card intended to determine the susceptibility of clinically significant yeasts to antifungal agents Fungal Susceptibility Card intended to determine the	

			Vitek 2 AST-ST01 Ref No: 410028 Shelf Life: 548 days Contents AM, P, CTX, CRO, CM, E, ICR, LEV, LNZ, TE, SXT, VA No. of Cards: 20 Cards **Vitek 2 AST-ST03** Ref No: 421040 Shelf Life: 548 days Contents: AM, P, CTX, CRO, C, CM, E, GM, ICR, LEV, LNZ, MXF, RA, TEC, TE, TGC, SXT, VA No. of Cards: 20 Cards Fee submitted: Rs. 25,000/-	susceptibility of clinically significant yeasts to antifungal agents Streptococcus Susceptibility Card intended to determine the susceptibility of S. pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus to antimicrobial agents Streptococcus Susceptibility Card intended to determine the susceptibility of S. pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus to antimicrobial agents	
218	-do- **<u>Evaluator</u>:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France Issued on 13.12.2017	VIDAS Cortisol S **VIDAS Cortisol S 30451** Class B Shelf Life: 7 months Rs.25,000/-	VIDAS Cortisol S is an automated quantitative test for use on the VIDAS family instruments, for the quantitative determination of cortisol in human serum,	**Approved** subject to provision of updated LOA, FQA or explanation from manufacturer.

				plasma (lithium heparin or EDTA) or urine using the ELFA technique.	
219	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France Issued on 13.12.2017	VIDAS® TOTAL IgE **VIDAS® TOTAL IgE 30419** Class B Shelf Life: 12 months Rs.25,000/-	VIDAS TOTAL IgE is an automated quantitative test for use on the VIDAS family instruments, for the immune enzymatic determination of total human IgE in human serum or plasma (lithium heparin or EDTA) using the ELFA technique.	**Approved** subject to provision of updated LOA, FQA or explanation from manufacturer.
220	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France Issued on 13.12.2017	VIDAS® Ferritin **VIDAS® Ferritin 30411** Class B Shelf Life: 12 months Rs.25,000/-	VIDAS Ferritin is an automated quantitative test for use on the VIDAS family instruments for the determination of human Ferritin in human serum or plasma (lithium heparin or EDTA) using the ELFA technique.	**Approved** subject to provision of updated LOA, FQA or explanation from manufacturer.
221	-do- **Evaluator:** Hafiz Muhammad	**Legal Manufactuer:** M/s. Sacace Biotechnologies s.r.l. via Santisi snc- 80024-	**SaMag Viral Nucleic Acid Extraction Kit** (Viral Nucleic Acid Extraction	SaMag Viral Nucleic Acids Extraction Kit is designed to be used with	**Approved.**

	Asif Iqbal [481]	santa gata' de' goti(bn), Italy. **Manufacturing site:** Via scala birini, 4422100, como, Italy FSC Italy Issued on 25.05.2018	Kit) Class B Shelf Life: 12 Months Codes: SM003 Rs.25,000/-	SaMag-12/24 automatic nucleic acid extraction system for the extraction of Viral DNA or RNA.	
222	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** M/s. Cepheid AB, Rontgenvagen 5, SE-171 54, Solna, Sweden. FSC Sweden Valid until 22.03.2020	**Xpert ® HPV** (Expert HPV Assay) GXHPV-CE-10 Class C Shelf Life: 18 Months Rs.50,000/-	The Xpert HPV Assay is a qualitative in vitro test for the detection of the E6/E7 region of the viral DNA genome from high risk.	**Approved** subject to provision of Full QA certificate.
223	M/s Digital Imaging System. 121, Habitat Apartment Shadman II, Ghaus-Ul-Azam Road, Lahore ELI- 00094 **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer**: Abbot Vascular, 3200 Lakeside Drive, Santa Clara, Falifornia, USA **Manufacturer Sites:** M/s Abbot Vascular Temecula 26531 Ynez Road Temecula, California 92591, USA FSC Belgium issued on 26-04-2019	Emboshield NAV6 Embolic Protection System Class D Sizes and Codes: Emboshield Nav 6, small, 2.5-4.8mm, 190 cm 22442-19 Emboshield Nav 6, large, 4.0-7.0 mm, 190 cm 22443-19 Shelf Life: 03 years Fee submitted: Rs. 50,000/-	A temporary percutaneous transluminal filtration system designed to be used as a guidewire and to capture embolic material released during an angioplasty and stent procedure within a saphenous vein bypass graft or a carotid artery	**Approved.**
224	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Abbot Vascular, 3200 Lakeside Drive, Santa Clara, Falifornia, USA **Manufacturer Sites**: M/s Abbot Vascular Temecula 26531 Ynez Road Temecula, California 92591, USA	BareWire Filter Delivery Wire Class D Sizes and Codes: BareWire FTW, Distal access, 190cm 22444-19 BareWire FTW, Workshorse, 190cm	A 0.014 inches PTFE coated stainless steel wire with a 3 cm platinum/nickel radiopague distal tip section used as part of Emboshield	**Approved .**

		FSC Belgium issued on 26-04-2019	22445-19 BareWire FTW, Workshorse, 315cm 22445-31 BareWire FTW, Support, 190cm 22446-19 Shelf Life: 03 years Fee submitted: Rs. 50,000/-	NAV6 Embolic Protection System	
225	-do- **Evaluator:** Ms. Unum Zia Shamsi	Legal Manufacturer: Abbot Vascular, 3200 Lakeside Drive, Santa Clara, Falifornia, USA Manufacturer Site: Abbot Vascular Temecula 26531 Ynez Road Temecula, California 92591, USA FSC Belgium issued on 02-05-2019	Supera Peripheral Stent System Class C Codes: 42045020-080 42045030-080 42045040-080 42045060-080 42045080-080 42045100-080 42045120-080 42045150-080 42055020-080 42055030-080 42055040-080 42055060-080 42055080-080 42055100-080 42055120-080 42055150-080 42055180-080 42055200-080 42065020-080 42065030-080 42065040-080 42065060-080 42065080-080 42065100-080 42065120-080 42065150-080 42065180-080 42065200-080 42075020-080 42075030-080 42075040-080 42075060-080 42075080-080 42075100-080	Indicated for peripheral vascular use following failed percutaneous transluminal angioplasty (PTA) and palliative treatment of biliary strictures produced by malignant neoplasms.	**Approved.**

			42045020-120 42045030-120 42045040-120 42045060-120 42045080-120 42045100-120 42045120-120 42045150-120 42055020-120 42055030-120 42055040-120 42055060-120 42055080-120 42055100-120 42055120-120 42055150-120 42055180-120 42055200-120 42065020-120 42065030-120 42065040-120 42065060-120 42065080-120 42065100-120 42065120-120 42065150-120 42065180-120 42065200-120 42075020-120 42075030-120 42075040-120 42075060-120 42075080-120 42075100-120 Shelf Life 02 years Fee submitted: Rs. 50,000/-		
226	M/s Intek CorporationOffice No. 30, First Floor, Al-Amin Plaza, The Mall Rawalpindi. ELI- 00034 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, 102200, China FSC Netherlands valid till23 June 2020	Brilliant Introducer Kit Class B Codes as per FSC Netherlands dated Nov 7, 2019. Certificate No. 26075 Shelf Life 03 years Fee submitted: Rs. 25,000/-	Intended for use to facilitate the introduction of guidewires, catheters and other accessory medical devices through the skin into vein or artery and minimize	**Approved.**

				blood loss associated with such introduction	
227	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, 102200, China FSC Netherlands valid till23 June 2020	**Lepu Medical-Contrast Medium Injection Manifold Kits** Class B Codes: MK-001- MK-002-MK-003- MK-004- MK-005- MK-006-MK-013- MK-014- MK-015- MK-016-MK-017- MK-018 MK-007- MK-008- MK-009- MK-010- MK-011- MK-012- MK-019- MK-020- MK-021- MK-022-MK023- MK-024 Shelf life: 3 years Fee submitted: Rs. 25,000/-	Indicated to provide injection channel for fluid and contrast transportation in interventional operation.	**Approved.**
228	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, 102200, China FSC Netherlands valid till23 June 2020	**SHOOCIN INTRODUCER KIT** Class B Codes as per FSC Netherlands dated Nov 7, 2019 Certificate No. 26075 Shelf Life: 03 years Fee submitted: Rs. 25,000/-	Indicated for use in arterial procedures requiring percutaneous introduction of intravascular devices	**Approved.**
229	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing,	**Lepu Medical-Inflation Device Kit** LP-P-30-YNP LP-P-30S-YNP LP-P-30-YNR LP-P-30S-YNR	Indicated for use in PCI to provide the pressure inside balloon	**Approved.**

		102200, China FSC Netherlands valid till 23 June 2020	LP-P-30-YNP20 LP-P-30S-YNP20 LP-P-30-YNP25 LP-P-30S-YNP25 LP-P-30-YNP40 LP-P-30S-YNP40 LP-P-30-YNP50 LP-P-30S-YNP50 LP-P-40-YNR LP-P-40S-YNR LP-P-40-YNP LP-P-40S-YNP LP-P-40-YNP20 LP-P-40S-YNP20 LP-P-40-YNP25 LP-P-40S-YNP25 LP-P-40-YNP40 LP-P-40S-YNP40 LP-P-40-YNP50 LP-P-40S-YNP50 LP-P-30-YNPH LP-P-30S-YNPH LP-P-30-YNRH LP-P-30S-YNRH LP-P-30-YNP20H LP-P-30S-YNP20H LP-P-30-YNP25H LP-P-30S-YNP25H LP-P-30-YNP40H LP-P-30S-YNP40H LP-P-30-YNP50H LP-P-30S-YNP50H LP-P-40-YNRH LP-P-40S-YNRH LP-P-40-YNPH LP-P-40S-YNPH LP-P-40-YNP20H LP-P-40S-YNP20H LP-P-40-YNP25H LP-P-40S-YNP25H LP-P-40-YNP40H LP-P-40S-YNP40H LP-P-40-YNP50H LP-P-40S-YNP50H		

			Class B Shelf Life: 03 years Fee submitted: Rs. 25,000/-		
230	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: NuMED, Inc. 2880 Main Street Hopkinton, NY 12965, USA FSC USA FDA valid till 20.05.2021	**CP Stent** (Sterile Cheatham Platinum Stent) Class D Codes: CP8Z16, CP8Z22, CP8Z28, CP8Z34, CP8Z39, CP8Z45, CP8Z50, CP8Z55, CP8Z60, CP10Z39, CP10Z45, CP10Z50, CP10Z55, CP10Z60 Shelf life 5 years Fee submitted: Rs. 50,000/-	CP stent (bare) is indicated for implantation in the native and/or recurrent coarctation of the aorta.	**Approved.**
231	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: NuMED, Inc. 2880 Main Street Hopkinton, NY 12965, USA FSC USA FDA valid till 20.05.2021	**BIB® Stent Placement Catheter** Size Codes: BB003, BB006, BB009, BB010, BB011, BB012, BB013, BB014, BB015, BB016, BB017, BB018, BB019, BB020, BB021, BB022, BB023, BB024, BB025, BB026, BB027, BB028, BB029, BB030, BB031, BB032, BB033, BB034, BB035, BB036, BB037, BB038, BB039, BB040, BB041, BB042, BB051, BB052, BB053, BB054,	Indicated for stent placement in vessels over 8mm in diameter	**Approved.**

			BB055, BB056, BB057, BB058, BB059, BB060, BB061, BB062, BB063, BB064, BB065, BB066, BB067, BB068, BB069, BB070, BB071, BB072, BB073, BB074, BB075, BB076, BB077. Class D Shelf life: 5 years Fee submitted: Rs. 50,000/-		
232	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: NuMED, Inc. 2880 Main Street Hopkinton, NY 12965, USA FSC USA FDA valid till 20.05.2021	**Covered CP Stent** Class D Codes: CVRDCP8Z16, CVRDCP8Z22, CVRDCP8Z28, CVRDCP8Z34, CVRDCP8Z39, CVRDCP8Z45, CVRDCP8Z50, CVRDCP8Z55, CVRDCP8Z60, CVRDCP10Z39, CVRDCP10Z45, CVRDCP10Z50, CVRDCP10Z55, CVRDCP10Z60. Shelf life: 05 years Fee submitted: Rs. 50,000/-	CP stent (bare) is indicated for implantation in the native and/or recurrent coarctation of the aorta and to maintain right ventricular outflow tract	**Approved.**
233	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** NuMED Canada Inc. 45 Second Street West Cornwall ON K6J IG3, Canada. FSC Canada issue date 2-6-2019	**PTS-X™ Sizing Balloon Catheter** Class D Codes: PTSX101, PTSX102, PTSX103, PTSX104, PTSX105, PTSX106, PTSX122, PTSX123, PTSX124, PTSX125, PTSX152,	Used in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.	**Approved.**

			PTSX153, PTSX154, PTSX155, PTSX156, PTSX157, PTSX203, PTSX204, PTSX205, PTSX206, PTSX253, PTSX254, PTSX255, PTSX256, PTSX303, PTSX304, PTSX305, PTSX306, PTSX307, PTSX308, PTSX353, PTSX354, PTSX355, PTSX356, PTSX357, PTSX358, PTSX359, PTSX360, PTSX403, PTSX404, PTSX405, PTSX406, PTSX407, PTSX408, PTSX409, PTSX410 Shelf life: 05 years Fee submitted: Rs. 50,000/-		
234	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** NuMED Canada Inc. 45 Second Street West Cornwall ON K61 IG3, Canada. FSC Canada Date of issue 6th Feb,2019	**Tyshak II PVT Catheter** (Tyshak II PTV Catheter) **Code:** (PDC500, PDC501, PDC502, PDC503, PDC504, PDC505,	The NuMEDTyshak II® catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. • A patient with isolated pulmonary	**Approved.**

			PDC506, PDC507, PDC508, PDC509, PDC510, PDC511, PDC512, PDC513, PDC514, PDC515, PDC516, PDC517, PDC518, PDC519, PDC520, PDC521, PDC522, PDC523, PDC524, PDC525, PDC526, PDC527, PDC528, PDC529, PDC530, PDC531, PDC532, PDC533, PDC534, PDC535, PDC536, PDC537, PDC538, PDC539, PDC540, PDC541, PDC542, PDC543, PDC544, PDC545, PDC546, PDC547, PDC548, PDC549, PDC550, PDC551, PDC552, SO001,SO002, SO003, SO004, SO007, SO008, SO009, SO014, SO017, SO018,	stenosis. • A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	

			SO019, SO020, SO021, SO029, SO030, SO031, SO032, SO033, SO034, SO035, SO036, SO037, SO038, SO069, SO086, SO100, SN001, SN002, SN003, SN004, SN005, SN006, SN007, SN008, SN009, SN010, SN011, SN013, SN11290. Class D Shelf life 05 years Rs.50,000/-		
235	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** NuMED Canada, Inc. 45 Second Street West Cornwall, ON K6J 1G3, Canada FSC Canada Date of issue 6th Feb. 2019	**Tyshak-Mini PTV Catheter** (Valvuloplasty Catheter) PDC400, PDC401, PDC402, PDC403, PDC404, PDC405, PDC406, PDC407, PDC408, PDC409, SO095, SO097, SO098, SO101, SO102, SO103, SO104 Class D Self life 5 Years Rs.50,000/-	The NuMEDTyshak Mini Catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in pediatric applications. • A patient with isolated pulmonary stenosis. • A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	**Approved.**
236	M/s. Verizon 60-D,FCC,	Manufacturer: Taewoong Medical	**Niti-S Pyloric/Duodena**	Intended for maintaiing	**Approved.**

	Zahoor Elahi Road, Gulberg IV, Lahore ELI 00087 **Evaluator:** Ms. Unum Zia Shamsi	Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	**l covered Stent (Both Bare-type)** Class C Codes: PS1806B, PS1808B, PS1810B, PS1812B, PS1814B, PS1815B, PS1816B, PS2006B, PS2008B, PS2010B , PS2012B, PS2014B, PS2015B, PS2016B, PS2206B, PS2208B, PS2210B, PS2212B, PS2214B, PS2215B , PS2216B, PS2406B, PS2408B, PS2410B, PS2412B, PS2414B, PS2415B, PS2416B, PS2606B, PS2608B, PS2610B, PS2612B, PS2614B, PS2615B, PS2616B, PS2806B, PS2808B, PS2810B, PS2812B, PS2814B, PS2815B, PS2816B, PST1806B, PST1808B, PST1810B, PST1812B, PST1814B, PST1815B,	pyloric/duodenum luminal patency caused by intrinsic and/or extrinsic benign stricture.	

			PST2006B, PST2008B, PST2010B, PST2012B, PST2014B, PST2015B, PST1806B-12, PST1808B-12, PST1810B- 12, PST1812B-12, PST1814B-12, PST1815B-12, PST2006B-12, PST2008B-12, PST2010B-12, PST2012B-12, PST2014B-12, PST2015B-12, PST1806B-22, PST1808B-22, PST1810B-22, PST1812B-22, PST1814B-22, PST1815B-22, PST2006B-22, PST2008B-22, PST2010B-22, PST2012B-22, PST2014B-22, PST2015B-22. Shelf life: 3 years Fee submitted: Rs. 50,000/-		
237	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	Niti-S Biliary Uncovered Stent (S-type) Class C Codes: T0604, T0605, T0606, T0607, T0608, T0609, T0610, T0612, T0804, T0805, T0806, T0807, T0808, T0809, T0810, T0812, T1004, T1005, T1006, T1007, T1008, T1009, T1010, T1012 B0604, B0605,	Intended for maintaining biliary luminal patency in malignant strictures.	**Approved.**

			B0606, B0607, B0608, B0609, B0610, B0612, B0804, B0805, B0806, B0807, B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009, B1010, B1012 BM0604, BM0605, BM0606, BM0607, BM0608, BM0609, BM0610, BM0612, BM0804, BM0805, BM0806, BM0807, BM0808, BM0809, BM0810, BM0812, BM1004, BM1005, BM1006, BM1007, BM1008, BM1009, BM1010, BM1012. Shelf life: 3 years Fee submitted: Rs. 50,000/-		
238	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	Niti-S Esophageal Uncovered Stent [Head Type] Class C Codes: E1006, E1008, E1010, E1012, E1014, E1015, E1206, E1208, E1210, E1212, E1214, E1215, E1406, E1408, E1410, E1412,	Intended for maintaining esophageal luminal patency in malignant strictures.	**Approved.**

			E1414, E1415, E1606, E1608, E1610, E1612, E1614, E1615, E1806, E1808, E1810, E1812, E1814, E1815, E2006, E2008, E2010, E2012, E2014, E2015, E2206, E2208, E2210, E2212, E2214, E2215, E2406, E2408, E2410, E2412, E2414, E2415, E2806, E2808, E2810, E2812, E2814, E2815 Shelf life: 3 years Fee submitted: Rs. 50,000/-		
239	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	**Niti-S Esophageal Covered Stent [Full Covered-Type]** Class C Codes: ES1006F, ES1008F, ES1010F, ES1012F, ES1014F, ES1015F, ES1206F, ES1208F, ES1210F, ES1212F, ES1214F, ES1215F, ES1406F, ES1408F, ES1410F, ES1412F, ES1414F, ES1415F, ES1606F, ES1608F, ES1610F, ES1612F, ES1614F, ES1615F, ES1806F,	Intended for the use in malignant and /or benign stricture and tracheoesopha geal fistula.	**Approved.**

			ES1808F, ES1810F, ES1812F, ES1814F, ES1815F, ES2006F, ES2008F, ES2010F, ES2012F, ES2014F, ES2015F, ES2206F, ES2208F, ES2210F, ES2212F, ES2214F, ES2215F, ES2406F, ES2408F, ES2410F, ES2412F, ES2414F, ES2415F, ES2806F, ES2808F, ES2810F, ES2812F, ES2814F, ES2815F, ESP1006F, ESP1008F, ESP1010F, ESP1012F, ESP1014F, ESP1015F, ESP1206F, ESP1208F, ESP1210F, ESP1212F, ESP1214F, ESP1215F, ESP1406F, ESP1408F, ESP1410F, ESP1412F, ESP1414F, ESP1415F, ESP1606F, ESP1608F, ESP1610F, ESP1612F, ESP1614F, ESP1615F, ESP1806F, ESP1808F, ESP1810F, ESP1812F, ESP1814F, ESP1815F,		

			ESP2006F, ESP2008F, ESP2010F, ESP2012F, ESP2014F, ESP2015F, ESP2206F, ESP2208F, ESP2210F, ESP2212F, ESP2214F, ESP2215F, ESP2406F, ESP2408F, ESP2410F, ESP2412F, ESP2414F, ESP2415F, ESP2806F, ESP2808F, ESP2810F, ESP2812F, ESP2814F, ESP2815F, EST1806F, EST1808F, EST1810F, EST1812F, EST1814F, EST1815F, EST2006F, EST2008F, EST2010F, EST2012F, EST2014F, EST2015F, EST1806F-18, EST1808F-18, EST1810F-18, EST1812F-18, EST1814F-18, EST1815F-18, EST2006F-18, EST2008F-18, EST2010F-18, EST2012F-18, EST2014F-18, EST2015F-18, EST1806F-22, EST1808F-22, EST1810F-22, EST1812F-22, EST1814F-22, EST1815F-22, EST2006F-22, EST2008F-22, EST2010F-22, EST2012F-22, EST2014F-22,		

			EST2015F-22,EST1806FR2, EST1808FR2, EST1810FR2, EST1812FR2, EST1814FR2, EST1815FR2, EST2006FR2, EST2008FR2, EST2010FR2, EST2012FR2, EST2014FR2, EST2015FR2 Shelf life 3 years Fee submitted: Rs. 50,000/-		
240	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	**Niti-S Pyloric/Duodenal Uncovered Stent [D-Type]** Class C Codes: PD1806, PD1808, PD1810, PD1812, PD1814, PD1815, PD2006, PD2008, PD2010, PD2012, PD2014, PD2015, PD2206, PD2208, PD2210, PD2212, PD2214, PD2215, PD2406, PD2408, PD2410, PD2412, PD2414, PD2415, PD2606, PD2608, PD2610, PD2612, PD2614, PD2615, PD2806, PD2808,	Intended for maintaining pyloric/duodenum luminal patency caused by intrinsic and/or extrinsic malignant or benign stricture.	**Approved.**

			PD2810, PD2812, PD2814, PD2815, PDT1806, PDT1808, PDT1810, PDT1812, PDT1814, PDT1815, PDT2006, PDT2008, PDT2010, PDT2012, PDT2014, PDT2015, PDT2206, PDT2208, PDT2210, PDT2212, PDT2214, PDT2215, PDT2406, PDT2408, PDT2410, PDT2412, PDT2414, PDT2415, PDT1806-12, PDT1808-12, PDT1810-12, PDT1812-12, PDT1814-12, PDT1815-12, PDT2006-12, PDT2008-12, PDT2010-12, PDT2012-12, PDT2014-12, PDT2015-12, PDT2206-12, PDT2208-12, PDT2210-12, PDT2212-12, PDT2214-12, PDT2215-12, PDT2406-12, PDT2408-12, PDT2410-12, PDT2412-12, PDT2414-12, PDT2415-12, PDT1806-22,		

			PDT1808-22, PDT1810-22, PDT1812-22, PDT1814-22, PDT1815-22, PDT2006-22, PDT2008-22, PDT2010-22, PDT2012-22, PDT2014-22, PDT2015-22, PDT2206-22, PDT2208-22, PDT2210-22, PDT2212-22, PDT2214-22, PDT2215-22, PDT2406-22, PDT2408-22, PDT2410-22, PDT2412-22, PDT2414-22, PDT2415-22. Shelf life: 3 years Fee submitted: 50,000/-		
241	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	Niti-S Enteral Colonic Covered Stent (Both Bare-type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2008B, CS2010B, CS2012B, CS2014B, CS2015B, CS2016B, CS2206B, CS2208B, CS2210B, CS2212B, CS2214B,	Intended for maintaining colon luminal patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign strictures.	**Approved.**

			CS2215B, CS2216B, CS2406B, CS2408B, CS2410B, CS2412B, CS2414B, CS2415B, CS2416B, CS2606B, CS2608B, CS2610B, CS2612B, CS2614B, CS2615B, CS2616B, CS2806B, CS2808B, CS2810B, CS2812B, CS2814B, CS2815B, CS2816B, CST1806B, CST1808B, CST1810B, CST1812B, CST1814B, CST1815B, CST2006B, CST2008B, CST2010B, CST2012B, CST2014B, CST2015B. Shelf life: 3 years Fee submitted: Rs. 50,000/-		
242	-do- **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	Niti-S Biliary Covered Stent (Full Covered-Type Class C Codes: TS0604F, TS0605F,TS0606F, TS0607F, TS0608F,TS0609F, TS0610F, TS0612F, TS0804F,	Intended for maintaining biliary luminal patency in malignant stricture	**Approved.**

			TS0805F, TS0806F,TS0807 F, TS0808F, TS0809F,TS0810 F, TS0812F, TS1004F,TS1005 F, TS1006F, TS1007F, TS1008F, TS1009F, TS1010F,TS1012 F, BS0603F, BS0604F, BS0605F, BS0606F, BS0607F, BS0608F, BS0609F, BS0610F, BS0612F, BS0803F, BS0804F, BS0805F, BS0806F, BS0807F, BS0808F, BS0809F, BS0810F, BS0812F, BS1003F, BS1004F, BSI005F, BS1006F, BS1007F, BS1008F, BS1009F, BS1010F, BS1012F, BSM0603F, BSM0604F , BSM0605F, BSM0606F, BSM0607F, BSM0608F, BSM0609F, BSM0610F , BSM0612F, BSM0803F, BSM0804F, BSM0805F, BSM0806F, BSM0807F,		

			BSM0808F, BSM0809F, BSM0810F, BSM0812F, BSM1003F, BSM1004F, BSM1005F, BSM1006F, BSM1007F, BSM1008F, BSM1009F, BSM1010F, BSM1012F Shelf life: 3 years Fee submitted: Rs. 50,000/-		
243	-do- **Evaluator:** Ms. Unum Zia **Rejected** as theSame Product by the same manufacturer has already been registered in the name of M/s Alliance Medical, Lahore Shamsi	Manufacturer: Taewoong Medical Co.,Ltd Head Office14,Gojeong-ro,Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Korea (Republic Of) FSC UK MHRA issued on 07.02.2019	**Niti-S Enteral Colonic Uncovered Stent [S-Type]** Class C Codes: CT1806, CT1808, CT1810, CT1812, CT2006, CT2008, CT2010, CT2012 Shelf life: 3 years Fee submitted: Rs. 50,000/-	Intended for maintaining colon luminal patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign stricture.	**Approved.**
244	M/s. A.H Distributors, House No. CB-708, Lane No. 5, 1st Floor, Peshawar Road, Rawalpindi. ELI-00225 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1st Road, Baolong Industrial Zone, Long gang District, 518116 Shenzhen, Guangdong, China. FSC U.K MHRA issued on 20-04-2017	Shunmei®Balloon Inflation Device Class B Codes: 617101 617102 617103 617108 617109 617110 617111 617112 Shelf Life: 03 years Fee submitted: Rs. 25,000/-	Intended to be used in PTCA operation, the balloon dilatation catheter is pressurized in order to achieve the expansion of blood vessels or the placement of intravascular stent.	**Rejected** as the same product by the same manufacturer has already been registered in the name of M/s Alliance Medical, Lahore.
245	-do- **Evaluator:** Ms. Hira	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B,	**Shunmei** (PTFE Coated Guide Wire) Codes as per FSC	PTFE coated Guide Wire is applicable as an invasive medical	**Rejected** as the same product by the same manufacturer has already been registered in the

	Bhutto	No.8 Jinglong 1st Road, Baolong Industrial Zone , LongGang District, 518116 Shenzhen, Guangdong, China. **Manufacturing Location:** M/s. Huizhou Branch of Shunmei Medical Co., Ltd., Vifa 3rd Road, Vifa Industrial Zone, Pingtan town, Huiyang District, Huizhou, guangdon, China. FSC U.K Issued on 20-04-2017	Class B Shelf Life: 03 years	Devices. It is indicated for guiding and assisting insertion of percutaneous catheter. Will not be used in central vasculature.	name of M/s Alliance Medical, Lahore.
246	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1st Road, Baolong Industrial Zone , LongGang District, 518116 Shenzhen, Guangdong, China. **Manufacturing Location:** M/s. Huizhou Branch of Shunmei Medical Co., Ltd., Vifa 3rd Road, Vifa Industrial Zone, Pingtan town, Huiyang District, Huizhou, guangdon, China. FSC U.K Issued on 20-04-2017	**Shunmei** (Connecting tube) Codes as per FSC Class B Shelf Life: 03 years	Connecting tubing is applicable as a non-invasive medical device. It is indicated for providing channel for infusion and pressure menitoring.	**Rejected** as the same product by the same manufacturer has already been registered in the name of M/s Alliance Medical, Lahore.
247	M/s NHK Health Care, Plot No. 63-C, Office No. 4, 2nd Floor,12th Commercial	Manufacturer: Yangzhou Super Union Import & Export Co. Ltd. No. 120, Xishan South Road, Chenji Town,	NHK Disposable Syringe (with needle) Class B	Sterile, single use syringe with needle	**Approved only 1cc and 10cc** subject to provision of stability studies supporting claimed shelf life.

	Street, DHA Phase II Ext. Karachi. (ELI applied) **Evaluator:** Ms. Unum Zia Shamsi	Yizeng City, Jiangsu Province, China FSC UK MHRA issued for Saudi Arabia (copy provided)	Sizes: 1cc, 2cc, 3cc, 5cc, 10cc G22, G23, G24, G25, G27, G30 Shelf life: 5 Years Fee submitted: Rs. 25000/-		
248	M/s. Al Waali Care Concepts, 86-Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi Shahu, Lahore ELI 00386 **Evaluator:** Ms. Unum Zia Shamsi	Manufacturer: Curatia Medical Limited. 198 Xiangjiang Road New District, Suzhou, Jiangsu, China, 215011. FSC China valid till 27-12-2020 FSC US FDA valid till 22.05.2021	Xcess Guiding Catheter Class D Sizes and codes as per US FDA CFG NO. 9755-5-2019 dated 23-05-2019 Shelf life: 3 years Fee submitted: Rs. 50,000/-	Sterile, single use, and guiding catheter intended to be used for intravascular introduction of interventional/ diagnoctic devices into the coronary or peripheral vascular systems.	**Approved** .
249	M/s. Total Technologies (Pvt) Ltd., 696, J-2, Johar Town, Lahore. ELI-00129 **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s. Flow-Meter S.p.A., Via del Lino 6, 24040 Levate (BG) Italy. FSC Italy Issued on 02.01.2019	**Flowmeter** (Vacuum Adjustment Systems) Vacuum regulator Easyvac Plus 250 Vacuum regulator Easyvac Plus 600 Class B Shelf Life: N/A Rs.25,000/-	Vacuum Adjustment Systems are particularly suitable for all medical suction applications in hospitals	**Deferred** for provision of codes on FSC.
250	M/s. Novatek Pakistan. P-20 Ist Floor, Chenab Market, Susan Road, Madina Town, Faisalabad. (ELI-00454)	**Legal Manufacturer:** M/s. BNOS Meditech Limited 9, Fifth Avenue, Bluebridge Industrial Estate, Halstead, Essex, UK. FSC U.K Issued on 15.04.2019	**Meditech** (Microvent Resuscitator) Class B Shelf Life: 15 years service life Rs.25,000/-	MicroVENT is a Pneumatic resuscitator intended for use by trained operator on patients suffering respiratory arrest or difficulties.	**Approved.**

	Evaluator: Ms. Hira Bhutto				
251	M/s Imtiaz Brothrs Suite, 7B, 2nd Floor, Abrar Business Center, 25-Mian Wahat Road Lahore ELI- 00133 **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: M/s Jiangsu Weikang Jiejing Medical Appaatus Co., Ltd 18 # Wenzhou Rd. Economic Development District Shuyange, (223600 Jiangsu,) republic of China FSC China Valid till 16th September ,2020	Drainage Tube (Drainage tube) Codes: Reference: Size 02044201: F24 02044202: F26 02044203: F28 02044204: F30 02044205: F32 Class B Shelf Life 05 years Rs.25,000/-	tube. Disposable Drainage tube is akind of medical device which is used to drain the urine from the body . Drainage tube also known as a chest tube or thoracic catheter is asterile tube that is inserted into the pleural space. The patient may require a chest drainage system any time the negative pressure in the pleural cavity is disrupted, resulting in respiratory distress.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and provision of stability data supporting shelf life of product. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
252	-do- **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: M/s Changzhou Kangxin Medical Insturments Co., Ltd Qiuzhuang, KLuoxi town Xinbei District , Changzhou, Jiangsu, China FSC China Valid date 19.03,2020	**SUCKERS** Suckers Size: L-1, L-2,S-1,S-2 Class B Shelf Life 03 years	Suckers are to provide blood suction to ensure a clear and dry surgical field. Suckers are used for attracting blood from the operating area in cardiac operation to ensure a clear vision	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and provision of Stability data supporting shelf life of product and FSC. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing

					plant.
253	M/s. M&M Pharma, Javaid Plaza, Opposite Pepsi Factory Gate #II, Guru Mangat Road, Gulberg II, Lahore. ELI-00159 **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** M/s. HLL Lifecare Limited, Akkulam Plant, Sreekariym P.O. Thiruvanathapuram – 695 017, Kerala State, India. **Manufacturing Site:** M/s. Akkulam, sreekariyam, P.O. thiruvananthapuram, Kerala, India-695017 FSC India Issued on 16.01.2019	**T-Care** (Cooper-T 380 A) Class D Shelf Life : 05 years Rs.50,000/-	It is intended for male to help prevent pregnancy and the transmission of sexually transmitted diseases.	**Approved** subject to foreign inspection of manufacturer and provision of Notarized full QA certificate & Original Notarized Credentials of manufacturer aboard. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
254	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer** M/s. HLL Lifecare Limited, Akkulam Plant, Sreekariym P.O. Thiruvanathapuram – 695 017, Kerala State, India. **Manufacturing Site:** M/s. Peroorkada, Thiruvananthapuram, Kerala, India-695005 FSC India Issued on 12.10.2018	**MOODS** (Male Lubricated Latex Comdoms) Class C Shelf Life : 05 years **Rs.50,000/-**	Male Lubricated Latex Comdoms. It is intended for male to help prevent pregnancy and the transmission of sexually transmitted diseases.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and provision of Notarized full QA certificate & Original Notarized Credentials of manufacturer aboard. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
255	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** Suzhou Colour-way enterprise DEVELOPMENT Co., Ltd 83-1	**M.Dior** (Male latex condoms)	It is intended for male to help prevent pregnancy and the transmission of	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents

		Changping Rd, Dongqiao area Xiangcheng District, Suzhou China FSC China Date of issue 24th April, 2017	Class : C Shelf life 5 Years	sexually transmitted diseases.	and provision of Notarized ISO 13485. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
256	M/s Galaxy Pharma (Pvt.) Ltd. D-180, Rojhan Street, Block 5, Clifton Karachi. (ELI-00402) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** SetpaTibbiGerecler ITH.IHR.SAN.VE.TI C.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC of Turkey issued on 05-04-2018) .	Neosilk Ultra Non-Absorbable Surgical Suture Class C Shelf Life: 3 years Code: Atraumatic Silk 3/0 26mm Curved cut 3/8 75cm sterile surgical suture Rs.50,000/-	Neosilk is a sterile, braided (twiseted in 8/0 and finer sizes) and non-absorbable surgical suture material that is composed of an organic protein called fibroin, derived from 100 % natural silk fibers obtained from the cocoons of silk worms by a special purification process called degumming.	**Deferred** for provision of EPSP, Manufacturing and QC documents, Proof of fee deposited & Stability data supporting shelf life of product.
257	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** SetpaTibbiGerecler ITH.IHR.SAN.VE.TI C.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC of Turkey issued on 05-04-2018) .	Neocryl Absorbable Surgical Suture PGA (Polyglycolic acid suture) Class D Shelf Life: 3 years Code: PGA (Polyglycolic acid) No: 1 30mm	Neocryl PGA is a sterile, synthetic, synthetic, braided and coated surgical suture material made of 100% Polyglycolic Acid. It is dyed in FDA approved (D & C violet no. 2) to make it easily distinguishable. Neocryl PGA is	**Deferred** for provision of EPSPand Stability data supporting shelf life of product.

			Round B.1/2 75cm sterile surgical suture Rs.50,000/-	suitable for use in applications like general wound closures, ophthalmic surgery, orthopedics, gynecology (episiotomy repair) and gastrointestinal tract surgery. It is not intended for use in cardiovascular or neurological surgery and thus should not be used in those procedures.	
258	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** SetpaTibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance)	Neoplene Ultra Non-Absorbable Surgical Suture (Polypropylene) Class: C Shelf Life: 3 years Code: Polypropylene 3/0 26mm curved cut 3/8 75cm sterile surgical suture Rs.50,000/-	Neoplene Polypropylene is a sterile, synthetic and monofilament non-absorbable surgical suture material made of polypropylene. It is dyed in blue or black to make it easily distinguishable. It is indicated for use in general soft tissue approximation. It is used in ophthalmic surgery, orthopedic plastic surgery, cardiovascular surgery and neurological surgery	**Deferred** for provision of EPSPand Stability data supporting shelf life of product.
259	M/s. Biocare Enterprises, Plot No. 64/2,	**Legal Manufacturer:** M/s. Meizhou Cornley Hi-Tech Co.,	**Electrolyte Analyser**	**Electrolyte Analyser**	**Deferred** for provision of Stability data

	Street No. 17, FECHS (Npf) 09, PWD Road, Islamabad. ELI-00220 **Evaluator:** Ms. Hira Bhutto	Ltd, Nanshan Industrial Estate, baigong, Meixian, Guangdon Province, China. FSC China Valid till 03-07-2019	Codes : AFT 300 AFT 500 Class B Shelf Life: Not mentioned		supporting shelf life of product (stability report of different solutions are mentioned which is not clear)
260	M/s Life-Tec Unit-B, 1st Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155 **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s Sichuan NIgale Biotechnology Co, Ltd, Office # 901-910,9/F,Unit 2, Bldg 1, No, 401 Sheng an street, Hi-Tech Dist.Chengdu, Sichuan, P.R, China. FSC China. Date of issue:3rd July, 2020	**NIGALE PLASMA/PLASMA SEPARATOR** **(Plasma Separator Machine)** **Code: XJC-2000 Digipla 90** **Class-C** Shelf Life: N/A	The Plasma Separator takes advantages of density difference of blood components of finish the process of centrifugation, separation, collection as well as returning rest components to blood donor. This equipment is indicated in collecting material plasma and preparing clinically fresh frozen plasma.	**Deferred** subject to foreign inspection of manufacturer and provision of Original notarized ISO 13485 and full quality assurance certificate. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
261	-do- **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: M/s Sichuan NIgale Biotechnology Co, Ltd Office # 901-910,9/F,Unit 2, Bldg 1, No, 401 Sheng an street, Hi-Tech Dist.Chengdu, Sichuan, P.R, China. FSC China. Date of issue:12th july, 2019	Nigale Platelet Apheresis Set/Kit (P-2000IA) (Disposal Blood Component APhereiss set)). Disposable blood Apheresis Kit is with ACD solution HS code: 9018909099.	This Platelet Apheresis Kit is being used in combination with ACD solution &NIgale Blood component Seprated Machine (XCF-3000)	**Deferred** subject to foreign inspection of manufacturer and provision of Original notarized ISO 13485, full quality assurance certificate and FSC.

			Class-C Shelf Life: 4 years		
262	-do- **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: M/s Sichuan NIgale Biotechnology Co, Ltd Office # 901-910,9/F,Unit 2, Bldg 1, No, 401 Sheng an street, Hi-Tech Dist.Chengdu, Sichuan, P.R, China. FSC China. Date of issue: 12th july, 2019	*Nigale Platelet/Blood Component Separator.* Blood Component Separator Machine (XCF-3000) Blood Component Separator Machine & NIgale Platelet apheresis/Blood Component apheresis Kit (P-2000IA) & with CDA solution. Class-C Shelf Life: N/A	The Machine is being used in combination with NIgale Disposalbe Blood Component apheresis set (p-2000IA) & with ACD solution also used for Mega Unit Platelets & RBC from blood.	**Deferred** subject to foreign inspection of manufacturer and provision of Original notarized ISO 13485 and full quality assurance certificate.
263	**M/s. DeKhon 11-C, Old FCC, Ferozpur, Road, Gulberg** **(ELI-00317)** **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. FSC – Neherlands Valid till 31st January,2021	Acrijet Green (acrijet Green 2.2) Class B Shelf Life: 3 years Rs.50,000/-	The Disposable AcriJet Green Premium cartridge & Injector Set ensures implantation of foldable IOLs in cataract surgeries.	**Approved** subject to provision of Stability data.
264	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands**.** **FSC – Neherlands** Valid till 31st	**Ocuva** (Ocuca A625) As per FSC Class-C Shelf Life: 3 years	It is indicated in cataract due to age as well as other cataract types.	**Approved.**

		January,2021	Rs.50,000/-		
265	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. FSC – Neherlands Valid till 31st January,2021	Protectalon (Protecalon 1.4%, Protectalon 2.0% , Protectalon 3.0%) Class C Shelf Life: 3 years Rs.50,000/-	Viuscoelastic sodium hyaluronate solution for intraocular use. It is used to to further nimize the risk of damage to the tissues of the eye during the surgical procedure. Instructions for Use Protectalon issterile , Non-pyrogenic, clear, high molecular weight, non-inflammatory, highly purified sodium, hyauoranate dissolved in a buffered physiological saline solution. It contains sodium hyluronate, sodium chloride, disodium hydrogenphos phate, sodium dihydrogen phosphate and water for injection	**Approved.**
266	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. FSC – Neherlands	**Acriva** Acriva UD 613 Acriva UDB 625) Acriva Reviol MFM 611 Acriva Reviol BB	IOL is indicated in cataract due to age as well as other cataract..	**Approved.**

		Valid till 31st January,2021	MFM 611 **Class-C** **Shelf Life:5 years** Rs.50,000/-		
267	M/s. Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi. ELI-00200 **Evaluator:** Ms. Hira Bhutto	**Manufacturer:** M/s. Nurteks Tekstil ve Medikal Sanayi Dis Tic. A.S., Kosklu Cesme, Mah. Yeni bagdat Cad. No. 124 Gebze / Kocaeli-Turkey. FSC Turkey Expiry on 5th December, 2020	**BROCHE** (Sterile disposable surgical drape and drape sets) Product Codes: 8698898292076, 8698898292021 8698898292106, 8698898292069 8698898291222 8698898291918, 8698898291895 8698898291970 8698898292137, Class B Shelf Life : 05 years Rs.25,000/-	Sterile drapes are used during surgery for stopping the contamination as preventing bacteria transfer coming from sick's skin and incision areas.	**Approved** subject to foreign inspection of manufacturer and provision of Stability studies, validation protocol and differential fee. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
268	M/s. Ameer Sons 305-A Upper Mall, Lahore (ELI-00058) **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer: OPTO-PHARMA PTE LTD 13 Tuas Ave 12 Singapore FSC – Singapore Issuance 4th January,2019	Opto-Pharm P2 Penta-Plex Multi-Purpose solution (No Rub) MPS 0350 MPS 0120 MPS 0010 Class C Shelf Life (MULTI DOSE) 48 months Shelf Life (UNI-DOSE, 10ml) 36 months Rs.50,000/-	As a cleaning, biofilm (protein and lipid) removing, disinfecting, storing, rinsing, wetting, lubricating, and comfort enhancing solution for all soft and hard contact lenses include disposable, colored and silicone hydrogel lenses.	**Approved** subject to foreign inspection of manufacturer. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
269	M/s. Mezan International 59 BR II, Opp.DCO,	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI	**ACTOSED FORTE READY-5L**	Aldehyde based ready to use disinfectant for	**Approved** subject to foreign inspection of manufacturer and

	House Haji Meherban Road, Jhelum ELI-00096. **Evaluator:** Shahid Muhammad Iqbal	TIC .A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey FSC Turkey Validity 16.03.2021	Pack Size, 5 liter 4250108303039 Class-C Shelf Life: 36 months Rs.50,000/-	medical instruments and endoscopes.	provision of stability study and ISO:13485. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
270	M/s Ghazi Brothers Ghazi house, D-35, KDA, Scheme No.1, Miran Muhammad Shah Road, Karachi. (ELI-00002) **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer:** Pronova Laboratories B.V. Kruitpad 16, 1398 CP MuidenThe Netherlands. FSC Netherland validity 02-05-2023	**Nailclin Nail Fungus Product** Class B Shelf Life: 36 Months Rs.25,000/-	Nailclin is a proven effective application that cures light to moderate nail fungus, when antimycotic drug preparations are unwanted, not effective and/ or contraindicated.	**Approved.**
271	M/s Briogene (Pvt) Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden Germany (FSC Germany issued on 21-02-2018)	QIAsymphony® DSP DNA Kit Class B Codes: QIAsymphony® DSP DNA Mini Kit (192)- 937236 QIAsymphony® DSP DNA Midi Kit (96)- 937255 Shelf Life: 24 Months Fee submitted: Rs. 5,000/-	Uses magnetic particle-technology for automated isolation and purification of DNA from biological specimens for in vitro diagnostic purposes	**Approved** subject to provision of differential fee and Form 7-A.
272	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden Germany (FSC Germany issued	QIAmp® DSP Virus Spin Kit Class B Code: 61704 50 tests Shelf life: 24	Uses silica-membrane technology for isolation and purification of viral nucleic	**Approved** subject to provision of differential fee and Form 7-A.

		on 21-02-2018)	Months Fee submitted: Rs 5,000/-	acids from biological specimens for in vitro diagnostic purposes	
273	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden Germany (FSC Germany issued on 21-02-2018)	QIAmp® DSP Virus Kit Class B Code: 60704 50 tests Shelf life: 24 Months Fee submitted: Rs 5,000/-	Uses silica-membrane technology for isolation and purification of viral nucleic acids from human plasma or serum samples for in vitro diagnostic purposes	**Approved** subject to provision of differential fee and Form 7-A.
274	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden Germany (FSC Germany issued on 21-02-2018)	QIAsymphony® DSP Virus/Pathogen Kit Class B Code: QIAsymphony® DSP Virus/Pathogen Mini Kit (192)-937036 QIAsymphony® DSP Virus/Pathogen Midi Kit (96)-937055 Shelf Life: 18 Months Fee submitted: Rs 5,000/-	Uses magnetic particle-technology for automated isolation and purification of viral and bacterial nucleic acids from biological specimens for in vitro diagnostic purposes	**Approved** subject to provision of differential fee and Form 7-A.
275	M/s Batla Impex, SH.40, Namco Centre, Cambell Street, Karachi. (ELI-00170) **Evaluator:** Hafiz Muhammad Asif Iqbal	**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: (6,8,10,12,14,16,18,20,22,24,26,28) Fr Rs.25,000/-	Foley Catheter (Urinary Catheter)	**Approved** subject to foreign inspection of manufacturer and provision of valid Free Sale Certificate. The Board also authorized the Secretary MDB to issue registration of the product, if the

					panel of experts approve the manufacturing plant.

Item No.XXVI.<u>RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

Secretary MDB informed the Board that the following applications for renewal of registration of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s K.S. Agencies, Suit# 210, 2nd Floor, Business Arcade, Main University Road Karachi. (ELI-00382) **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Glylon (Nylon Monofilament Polyamide) Synthetic non-absorbable surgical suture Class C Shelf Life: 5 years Sizes as per FSC	For Skin Closure in general surgery, plastic surgery, gastrointestinal surgery, gynecology, obstetrics & orthopedics.	**Approved** subject to foreign inspection of manufacturer and provision of Notarized ISO, FQA, Mnaufacturing and QC documents, Stability data, EPSP and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
2.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City	Glylene Monofilament Polypropylene non absorbable surgical suture	For use in general soft tissue approximation and / or ligation,	**Approved** subject to foreign inspection of manufacturer and provision

		China. (FSC China Valid Till 17-01-2021)	Class C Shelf Life: 5 years Sizes as per FSC	including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissue.	of Notarized ISO, FQA, Stability data, EPSP and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
3.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Glytin Polyglycolic Acid Synthetic absorbable suture Class D Shelf Life: 6 years Sizes as per FSC	This is a sterile thread made from polyglycolic acid that is used to join the edges of a wound or incision by stitching. General soft tissue approximations and or ligation, especially in general surgery, skin closures, Gastrointestinal surgery, Gynaecology, Obsterics, plastic surgery, Urology, ophthalmic surgery and orthopaedics.	**Approved** subject to foreign inspection of manufacturer and provision of NotarizedISO, FQA, Design examination, Mnaufacturing and QC documents,EPSP and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
4.	-do- **<u>Evaluator</u>:**	**Legal Manufacturer:** Huaiyin Medical	Catgut Chromic Catgut Chromic	Suture, absorbable, non-synthetic,	**Approved** subject to foreign

	Ms. Hira Bhutto	Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Class D Shelf Life: 5 Years Sizes as per FSC	pseudo-monofilament, treated with chromic salts to retard absorption, with surgeon able to choose appropriate thread diameter and length according to surgical requirement. Surgical procedures for tying off, ligaton and or tissue approximation .	inspection of manufacturer and provision of Notarized ISO, FQA, Design examination, Mnaufacturing and QC documents and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
5.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Glyster Braided Polyester Class C Shelf Life: 5 Years Sizes as per FSC	Coated braided, non-absorbable sterile surgical suture. Available with or without needles. The needles may be attached permanently or as a control release which enables the needles to be pulled off instead of being cut off. The suture is coated with polybutylate which acts as lubricant to mechanically improve the ease of passage	**Approved** subject to foreign inspection of manufacturer and provision of Notarized ISO, FQA, manufacturing and QC documents, Stability data, EPSP and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the

				through tis sue and the overall handling qualities of the suture.	manufacturing plant.
6.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Catgut plain Catgut plain Class C Shelf Life: 6 Years Sizes as per FSC	Absorbable sterile suture composed of purified connective tissue derived from the serosal layer of bovine or the submucosal layer of Bovine intestines. Plain Surgical Gut Suture have tensile strength retention of 7-10 days and an absorbption time of 70 days	**Approved** subject to foreign inspection of manufacturer and provision of Notarized ISO, FQA, manufacturing and QC documents, EPSP and original registration letter. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
7.	-do- **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal Manufacturer:** Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China. (FSC China Valid Till 17-01-2021)	Glysilk Braided Silk Natural non absorbable sterile surgical suture Class C Shelf Life: 5 Years Sizes as per FSC	Braided Silk surgical suture used in surgical procedures for tying off, ligation and or tissue approximation , available in diameters and lengths according to surgical requirements	**Approved** subject to foreign inspection of manufacturer and provision of Notarized ISO, FQA, Manufacturing and QC documents, and original registration letter. The Board also authorized the Secretary

					MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.

Item No. XXVII.<u>REGISTRATION OFMEDICAL DEVICES FOR LOCAL MANUFACTURER</u>

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for local manufacture on prescribed form 7 under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Remarks
1.	M/s Faisal Pharmaceutical Industries, 602-B, S.I.E, Sargodha Road, Faisalabad. **<u>Evaluator</u>:** Ms. Unum Zia Shamsi	Septigras Chlorhexidine Acetate (Antiseptic Tulle Dressing) Sizes: 10 cm x 10 cm Tulle 10 cm x 30 cm Tulle 15 cm x 20 cm Tulle 15 cm x 15 cm Tulle 10 cm x 1 m (Roll) 10 cm x 2 m (Roll) 15 cm x 1.5 m (Roll) Class C Shelf Life: 2 Years Fee submitted: 20,000/-	Sterile tulle dressing containing Chlorhexidine Acetate 0.5% to be used primarily on minor cuts and burns and also on other types of wounds, such as pressure sores and leg ulcers	**Approved** only for export purpose.
2.	-do- **<u>Evaluator</u>:** Ms. Unum Zia Shamsi	Silvograss Tulle Sizes: 10 cm x 10 cm Tulle 10 cm x 30 cm Tulle 15 cm x 20 cm Tulle 15 cm x 15 cm Tulle 10 cm x 1 m (Roll) 10 cm x 2 m (Roll) 15 cm x 1.5 m (Roll) Class C	Sterile tulle dressing containing Silver Sulphadiazine 1% to be used primarily on second and third degree burns and also on other types of wounds, such as pressure sores and leg ulcers	**Approved** only for export purpose.

		Shelf Life: 2 Years Fee submitted: 20,000/-		
3.	M/s Asian Fibre, Plot No. 41-42, Sector 25, K.I.A, Karachi **Evaluator:** Ms. Unum Zia Shamsi	Detex Gauze swab sponges Gauze 2" x 2" (8ply) Gauze 3" x 3" (8ply) Gauze 3" x 3" (12ply) Gauze 3" x 3" (16ply) Gauze 4" x 4" (8 ply) Gauze 4" x 4" (12 ply) Gauze 4" x 4" (16 ply) Class B Shelf life: 2 years (undertaking provided) Fee submitted: Rs. 5,000/-	Absorbent cotton gauze dressing with integrated x-ray detectable thread. Non-sterile	**Approved** only for export purpose.

Item No. XXVIII. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER

Secretary MDB informed the Board that the following applications for grant of enlistment medical devices for local manufacture on prescribed form 6 under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

Sr No.	Name and Address of Firm	Name of Medical Device	Brief Description/ Shelf Life/ Class of MD	Remarks
1.	M/s Asian Fibre, Plot No. 41-42, Sector 25, K.I.A, Karachi **Evaluator:** Ms. Unum Zia Shamsi	Ortho-Cast (Orthopaedic casting tape) Ortho Cast 2" x 4 yard Ortho Cast 3" x 4 yard Ortho Cast 4" x 4 yard Ortho Cast 5"x 4 yard Class A Shelf life: 2 years (undertaking provided) Fee submitted: Rs. 5,000/-	Used for construction of common orthopedic casts, plastic surgery and for the external fixation of fractures and sprains	**Approved** subject to GMP inspction.
2.	-do-	Softban Under-Cast Padding	Used as a pad for orthopedic casting tape	**Approved** subject to

	Evaluator: Ms. Unum Zia Shamsi	Under-Cast 2" Under-Cast 3" Under-Cast 4" Under-Cast 6" Class A Shelf life: 2 years (undertaking provided) Fee submitted: Rs. 5,000/-	and splint or plastic bandage	GMP inspction.

Item No. XXIX.EFERRED CASES IN MDB 14th MEETING OF M/S JOHNSON & JOHNSON

The below mentioned products of M/s Johnson & Johnson was deferred in 14th Meeting of MDB due to clarification regarding codes of medical devices:-

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. Highway 183 Km, 8.3 San Lorenzo, PR USA 00754. **Manufacturing Site:** Ethicon, LLC. Highway 183 Km 8.3 San Lorenzo, PR USA 00754. (FSC USFDA valid 03-04-2021)	Prolene™ Polypropylene Mesh Codes: PMM3 (CE-marked) PMS1 (CE-marked) PMM1(CE-marked) PMSK1(CE-marked) PML1(CE-marked) PMS3 (non-CE marked) PMH (non-CE marked) PMII (non-CE marked) PMLK (non-CE marked) PMXL (non-CE marked) PMXS (non-CE marked) Class C Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Used for the repair of hernia and other fascial deficiencies that requires the addition of a reinforcing or bridging material to obtain the desired surgical result repair. Sterile	**Deferred** for clarification regarding codes of medical device.
-do- **Evaluator:** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA, 00754.	PROLENE ™Polypropylene Suture (Polypropylene, Monofilament, Sterile, Synthetic, Non-Absorbable Surgical	A monofilament, synthetic, non-absorbable, sterile surgical suture composed of	**Deferred** forclarification of codes of medical device.

	Manufacturing Site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA, 00754. (FSC US FDA valid till 03-04-2021)	Suture) Class D Codes: 8434H 8435H 8521H 8522H 8556H 8623H 8632G 8634G 8635G 8702H 8706H 8833H EP8704H W1713 W2777 W525 W527 W621 W8003T W8005T W8006T W8007T W8010T W8014T W8020T W8021T W8025T W8026T W8101 W8305 W8307 W8310 W8316 W8329 W8330 W8340 W8430 W8522	an isotactic crystalline stereoisomer of polypropylene. For use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.	

		W8525 W8549 W8556 W8557 W8558 W8571 W8597 W8623 W8683 W8689 W8697 W8702 W8703 W8704 W8706 W8707 W8710 W8721 W8731 W8761 W8802 W8803 W8807 W8831 W8840 W8937 W8977 8357H 8634H W8430G W8307G W8731G W8761G 8686H Shelf Life: 60 Months Fee submitted: Rs. 50,000/-		
-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Johnson and Johnson	Ethicon® Monocryl ™ Plus Antibacterial (Poliglecaprone 25) Suture	Sterile, synthetic, absorbable monofilament	**Deferred** for clarification of codes of medical device.

	International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium **Manufacturing Site:** Johnson and Johnson Medical Limited, Simpson Parkway, Kirkton Campus, Livingston, Scotland, EH54 7AT, United Kingdom (FSC Belgium issued on 3-5-2019)	Class D Codes: MCP3205G MCP3650G MCP500H Shelf Life: 5 years Fee submitted: Rs. 50,000/-	suture prepared from a co-polymer of glycolide and e-caprolactone. Intended for use in general soft tissue approximation and/or ligation wherein an absorbable material is indicated	

The matter is placed before the MDB for consideration.

Decision: The Board approved the above products of M/s J&J Pakistan.

MINUTES OF ADDITIONAL AGENDA FOR 15TH MEDICAL DEVICE BOARD MEETING HELD ON 30TH DECEMBER, 2019

Agenda Item NO:1

Registration of class D and Class B medical devices to be imported.

S No:	Name Of Importer	Manufacturer Details	Device details	Brief description	Decisions
1	**DIGITAL IMAGING SYSTEMS** 121 Habitat Apartments, Shadman II,Ghaus-ul-Azam Road , Lahore-54000, Pakistan, Licence no: **ELI-00094** Date of Issuance: **03-08-2018** **Evaluator: Mrs Hira Bhutto**	**1. Legal Manufacturer: ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site: ABBOTT VASCULAR** 3885 BOHANNON Drive Menlo Park, CA USA 94025	**MITRACLIP NTR CLIP DELIVERY SYSTEM** Codes: CDS0602-NTR, CDS0601-NTR Class: D Shelf Life: 01 year Fee: 50000/-	Mitra Clip is intended for reconstruction of the insufficient mitral valve through tissue approximation. The Clip Delivery System is used to advance and manipulate the implantable Mitra Clip Implant for proper positioning and placement on the mitral valve leaflets.	Approved only with code CDS0601-NTR
2	-do-	**1. Legal Manufacturer: ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site: ABBOTT VASCULAR** 3885 BOHANNON Drive Menlo Park, CA USA 94025	**MITRACLIP XTR CLIP DELIVERY SYSTEM** Codes: CDS0602-XTR, CDS0601-XTR Class: D Shelf Life: 01 year Fee: 50000/-	Mitra Clip is intended for reconstruction of the insufficient mitral valve through tissue approximation. The Clip Delivery System is used to advance and manipulate the implantable Mitra Clip Implant for proper positioning and placement on the	Approved only with code CDS0601-XTR

				mitral valve leaflets.	
3	-do-	**1. Legal Manufacturer:** **ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site:** **ABBOTT VASCULAR** 3885 BOHANNON Drive Menlo Park, CA USA 94025	**MITRACLIP STEERABLE GUIDE CATHETER** Code: SGC0301, SGC0302 Class: D Shelf Life: 01 year Fee: 50000/-	MitraClip is intended for reconstruction of the insufficient mitral valve through tissue approximation. The Clip Delivery System is used to advance and manipulate the implantable Mitra Clip Implant for proper positioning and placement on the mitral valve leaflets.	Approved only with code SGC0301
4	-do-	**1. Legal Manufacturer:** **ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site:** **ABBOTT VASCULAR** 3885 BOHANNON Drive Menlo Park, CA USA 94025	**MITRACLIP ACCESSORY-LIFT** Code: LFT01ST Class: A Shelf Life: N/A Fee: 5000/-	MitraClip Reusable Accessories are intended to provide a stable platform to support the MitraClip Delivery System.	Approved
5	-do-	**1. Legal Manufacturer:** **ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site:** **ABBOTT VASCULAR** 3885 BOHANNON Drive Menlo Park, CA USA 94025	**MITRACLIP ACCESSORY-SUPPORT PLATE** Code: PLT01ST Class: A Shelf Life: N/A Fee: 5000/-	MitraClip Reusable Accessories are intended to provide a stable platform to support the MitraClip Delivery System.	Approved
6	-do-	**1. Legal Manufacturer:** **ABBOTT VASCULAR** 3200 Lakeside drive, Santa Clara , CA 95054 2. **Manufacturing Site:**	**MITRACLIP ACCESSORY-STABILIZER** Code: SZR01ST	MitraClip Reusable Accessories are intended to provide a stable	Approved

		ABBOTT VASCULAR 3885 BOHANNON Drive Menlo Park, CA USA 94025	Class: A Shelf Life: N/A Fee: 5000/-	platform to support the MitraClip Delivery System.	

Agenda Item No: II

Advisory for Provinces regarding the sale of contraceptive device (i.e Condoms)

Ever since the notification of SRO: 824(I)/2018 dated 26th June, 2018 the sale of the contraceptive device (i.e Condoms) has been restricted to pharmacies only considering them as a therapeutic goods due to which their availability to the public at large is been greatly affected. To ensure the access to the said device for the population Medical Device Board may recommend the issuance of an advisory for the Provincial Healthcare Departments to allow its sale over the counter in the open market.

Submitted for deliberation of Medical Device Board.

Decision: The matter is deferred due to paucity of time.

Agenda Item No: III

Indenting of medical devices by Hospitals, Institute or Charitable trust

Under Rule 72 (2) of Medical Devices Rules, 2017 rephrased as under :-

(2) Where an institute, hospital, a registered charitable trust or institution intends to import medical devices through an indenter, the MDB may allow such indenting subject to the condition that such medical devices imported through indenting shall not be sold for commercial purpose in the open market.

It is submitted that currently most of the hospitals/institutions are importing medical devices through indenting and are being released subject to "NOT TO DISPOSE OF" without consent of the MDB. To facilitate the hospitals/institutions it is proposed that the MDB may authorize the Additional Director (MDMC)/Secretary MDB to issue such indenting with the approval of CEO, DRAP, Islamabad. The hospitals/institutions will submit the following documents for the purpose:-

a) Request of the hospitals/institute on their letter head.
b) Purchase order of medical devices to be indenting in the name of hospital.

c) Undertaking on stamp paper that such medical devices imported through indenting shall not be sold for commercial purpose in the open market

d) Proof of registration of medical devices and license of importer (indenter).

Submitted for consideration/approval of MDB please.

Decision: The matter is deferred due to paucity of time.

Agenda Item No: IV

IMPLEMENTATION ON NATIONAL ACTION PLAN TO ADDRESS UNSAFE INJECTION SAFETY IN PAKISTAN

Reference to the launch of National action Plan of injection safety by Ministry of National Health Services, Regulations and Coordination has conveyed that there are certain issues to be addressed by Drug regulatory authority for implementation of unsafe injection practices across the country

(i) Issue: Imported Auto Disable (AD) syringes must meet minimum ISO standards (13485, 9269, 0993)

DRAP may revisit the dossier of all importers to ensure that CE ISO standard for imported AD are maintained.

(ii) Issue: Local manufacturers are permitted to manufacture 2, 2.5. 3 and 5ml disposable syringes till 31st March, 2020.

DRAP may place this agenda item in the next meeting of Policy Board. The advice will entail instructions from DRAP to local manufacturers to completely stop the manufacturing of disposable syringes of 2, 2.5, 3 and 5 ml disposable syringes and encourage the local production of the same in Auto-disable format. The instructions will come into effect from 31st March, 2020.

(iii) Issue: Currently most of the local disposable syringes are manufactured below the minimum standard of ISO 13485.

There are two certifying bodies that are internationally recognized for inspection, verification, testing and product certification of medical devices and syringes namely SGS and TUV. Both of these bodies are present in Pakistan and have to be registered

with Pakistan National Accreditations Council (PNAC) before they can be given the task of ISO.13485 and CE certification of all local manufacturers. DRAP is advised to initiate procedure to register both the companies after accreditation to ensure quality production of AD syringes ensuring that required rules/regulations are followed.

Decision: The matter is deferred due to paucity of time.

==========