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

### MINUTES OF THE 15<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 30-12-2019

15<sup>th</sup> 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 30<sup>th</sup>December, 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:-

<b>S.No</b> .	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. <u>CONFIRMATION OF MINUTES OF 14<sup>TH</sup> MEDICAL DEVICE BOARD</u> <u>MEETING.</u>

**Decision:** The Board confirmed the minutes of the 14<sup>th</sup> meeting of MDB.

### Item No. II. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT</u> <u>MEDICAL DEVICES.</u>

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	<b>Approved</b> for storage of warm range medical devices without cold chain facility
3.	M/s Advance System, 630 Shadman Colony-1, Lahore.	<ol> <li>Sabir Ali Hussain</li> <li>Mahboob Haider</li> <li>Ammar Alam.</li> <li>Waseem Mazhar</li> <li>Mirza</li> <li>Anbreen Zafar.</li> </ol>	-do-	No	Rejected,asthestorageconditionsatthepremiseswerenotsatisfactory;theceilingofstorestore

	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, 1 <sup>st</sup> floor, KH 2312, Tape Road, Sheesh Mehal, Near UVAS, Lahore. <b>Godown:Same</b>	Mr. Mohammad WaseemTipu	-do-	No	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.
5.	As above M/s Opti Med, 2 <sup>nd</sup> Floor Hassan Plaza 6-A Jail Road, Lahore. Godown:Same As above	Mr. Shafique Ur Rehman	-do-	No	<b>Approved</b> 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	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.
8.	M/s FDS (Pvt) Ltd., Flat No.8, 1 <sup>st</sup> 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	<ol> <li>Dr. Shahla Javed</li> <li>Mr. Saad Javed Akram</li> <li>Mr. Abdul Shabbir Khokhar</li> </ol>	Mr. Shoaib Ahmed, FID, DRAP, Lahore. Mrs. Anam Saeed, AD, DRAP, Lahore.	No	Approved for storage of non-cold chain medical devices only.
10.	as Above 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. <b>Godown:</b> 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<), DRAP, Islamabad.	No	Approved for storage of room temperature medical devices without cold chain facility.

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

P H V R C P In	ystems (SMC) Pvt. Ltd, 111-B, Hali Road, Vestridge-1, Rawalpindi. Godown: Plot No.36, ndustrial Estate, Vah Cantt.				temperature medical devices without cold chain facility subject to provision of copy of DSL.
16. M M H B F Ja	Van Cantt. A/s Oasis Aedical System, House No. A-86, Block C, Ground Floor, Gulshan-e- amal, Karachi. Godown: Same s 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.
P (I C P S S K C P B B P S	M/s R.G. Pharmaceutica Pvt). Ltd, Head Office. No. 703, Progressive Equare, Block-6, P.E.C.H. S, Shahrah-e-Faisal, Karachi. <b>Fodown</b> : 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 M 3: Ju P B R R C L R R P B B	A/s Aswad Medical Co. C-2, rd Floor, Rahat o Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi. <b>Godown:</b> <b>D-5, 4th Floor,</b> Rahat Jo Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi.	Muneeza Saleem.	-do-	No	<b>Approved</b> for storage of warn range temperature medical devices without cold chain facility.
19. N	M/s Sawanki & Co, C-211,	Mr. Kafeel Ahmed	-do-	No	Approved for storage of room

	Sector 35-A Korangi, Township, Karachi. <b>Godown</b> : 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. <b>Godown</b> : 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, 1 <sup>st</sup> Floor,S.M.C.H.S , Karachi, <b>Godown</b> : 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. <b>Godown</b> : Same as Above	Muhammad Shariq Mrs. Seema Imran Mr. Muhammad Imran Yousaf.	-do-	No	<b>Approved</b> 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. <b>Godown</b> : Same as Above	Mr. Mufaddal Feroze Cutlerywala.	-do-	Yes	<b>Approved</b> 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 7 <sup>th</sup> Floor, KS Trade Tower, Shahra-e- Liaquat, Karachi. <b>Godown</b> : Same as Above				temperature medical devices without cold chain facility.
25.	M/s Arfi International, Office No. 904, 9th Floor, A1 Rahim Tower, I. I. Chandrigar Road, Karachi. <b>Godown</b> : Same as Above	Mr. Altaf Gauhar Paracha	-do-	No	<b>Approved</b> 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. <b>Godown</b> : 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. <b>Godown</b> : Same as Above	Mr. Fakhar Islam	-do-	No	<b>Approved</b> 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.	Dr. Sarah Saleem Mr. Afshaan Haroon Jafri. Jameel Yousaf.	-do-	No	Approved for storage of room temperature medical devices without cold chain facility.
	<b>Godown</b> : Basement Plot No.C-21, Sector				

	6-F, Mehran Town, Korangi Industrial Area, Karachi.				
29.	M/s Health Services, Apartment No. A-3, (3 <sup>rd</sup> Floor) Plaza No. 08, Civic Centre, Phase IV, Bahria Town, Islamabad. <b>Godown</b> : Same as Above	Mr. Haroon-ur- Rasheed	Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad. Mr. Ishtiaq Shafiq, Assistant Director (QA<), 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. <b>Godown</b> : Same as Above	Mr. Nasir Ali	-do-	No	<b>Approved</b> 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. <b>Godown</b> : 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	<b>Approved</b> 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 Aboye				
33.	M/s RA Healthcare (SMC-Pvt) Ltd, 2 <sup>nd</sup> Floor, Building No. 50, Mir Arcade, Mini Commercial, Phase 7, Bahria Town, Islamabad. <b>Godown</b> : 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, 3 <sup>rd</sup> 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	<b>Rejected</b> 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	were not met. Approved for storage of room temperature medical devices without cold chain

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	Phase-VI,				facility.
	D.H.A, Karachi				
	Godown: Same				
	as Above				
26	M/a Coursi	Mahain Ohani	do	N	A
36.	M/s Surgi Pharm, B-1&2, Basement Floor, Plot No. 34-C, Rahat Commercial Lane No-2, Phase VI, DHA, Karachi.	Mohsin Ghani Sodagar	-do-	No	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.
	<b>Godown</b> : Same as Above				
37.	M/s Bone Solution, Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A. Karachi.	Mr. Zain Iqbal Mr. Zafar Iqbal	-do-	No	<b>Approved</b> for storage of warn range temperature medical devices without cold chain facility.
	<b>Godown</b> : Same as Above				
38.	M/s Surgilink, Shop No. 234, 2 <sup>nd</sup> Floor, International Centre, Saddar, Karachi.	Muhammad Saeed	-do-		<b>Rejected</b> 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. <b>Godown</b> : 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, 1 <sup>st</sup> Floor, Al- Rehman Trade Centre, Shahrah- e-Liaquat, Opp,	Mr. Nasir Mehmood	-do-	No	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.

	Sindh Madrasa, Karachi. <b>Godown:</b> Office No.214, 2nd Floor, A1- Rehman Trade Centre, Shahrah- e-Liaquat, Opp, Sindh Madrasa, Karachi.				
43.	M/s Global Technical Services, Suite No. 1 & 2, 3 <sup>rd</sup> Floor, Nadir House, I.I.Chandrigar Road, Karachi. <b>Godown</b> : 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 14 <sup>th</sup> , Phase V, D.H.A., Karachi. <b>Godown</b> : 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. <b>Godown</b> : 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.,				without cold chain
	Karachi.				facility.
	<b>Godown</b> : Same as Above				
47.	M/s Siddiqui& Company, Plot No.3-C-9/3B, Shumail Terrace, Nazimabad No.3, Karachi. <b>Godown</b> : Same as Above	Mr. Amir Anis Mr.Khurram Anis	-do-	No	<b>Approved</b> 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. <b>Godown</b> : Same as Above	Muhammad Umer Muhammad Iqbal Badaruddin Liaquat Ali Malik Muhammad Ali Malik	-do-	Yes	<b>Approved</b> 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<), DRAP, Islamabad.	No	<b>Rejected</b> 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.

	<b>Godown</b> : Same as Above				
52.	M/s Multi Pharma, D- 206/2 Satellite Town, Rawalpindi.	Mr. Khalid Javed Kiani	-do-	No	<b>Rejected</b> 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, 1 <sup>st</sup> Floor, Chandi Chowk, Rawalpindi	Mr. Babar Shahzad.	-do-	No	<b>Rejected</b> 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. <b>Godown</b> : Same as Above	Mr. Nabi Amin Mr.Zia-ur-Rehman	-do-	<u>No</u>	<b>Approved</b> 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. <b>Godown</b> : Same as Above	Ehtesham Rauf Malik Amjad Tahir Irfan Qureshi	-do-	No	<b>Approved</b> 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,	<u>No</u>	<b>Approved</b> 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.	<b>Rejected</b> 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. <b>Godown</b>	Ms. Rukhshanda Azam	-do-	No	<b>Approved</b> for storage of warm range medical devices without cold chain facility.
	Address: A-406, Billy's Shopper's Galleria and				

	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	<b>Approved</b> 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, 4 <sup>th</sup> Floor, Plot No. 37-C, Stadium Lane, Comm. Area, Phase V, DHA, Karachi. <b>Godown</b> 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-	<u>No</u>	<b>Approved</b> 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. <b>Godown</b> Address: 28/29,Timberpo n, Kiamari, Karachi.	Mr. Abdul Majid Carim. Mr. Sohail Majid Carim.	-do-	No	Approvedfor 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	<b>Approved</b> 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 4 <sup>th</sup> Floor Karachi Market Khyber Bazar, Peshawar. <b>Godown:</b> Same as above.	Syed Rizwan Ali Shah	-do-	Yes	<b>Approved</b> 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. <b>Godown:</b> 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. <b>Godown</b> : Same as above.	Mr. Naeem Ullah	-do-	<u>No</u>	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-	<u>No</u>	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, 2 <sup>nd</sup> 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, 3 <sup>rd</sup> Floor Room No. 303, Namak Mandi Peshawar. <b>Godown</b> : Same	Mr. Jan Alam	-do-	No	Approved for storage of room temperature medical devices without cold chain facility.
78.	as above. M/s Shahid Surgical, Basement Abdul Market, Shop No. 14, Namak Mandi Peshawar. <b>Godown</b> : 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. <b>Godown</b> : 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, 1 <sup>st</sup> Floor, Al-Jalil Market, Namak Mandi, Peshawar. <b>Godown</b> : 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.

	<b>Godown</b> : 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	<b>Approved</b> 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	<b>Approved</b> 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. <b>Godown:</b> 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, 4 <sup>th</sup> Floor, Karachi Market, Khyber Bazar, Peshawar. <b>Godown:</b> 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
			ivialialiana iqual,		storage of room

88.	09-10 Nawab Plaza Shalley Velly Range Road Rawalpindi. <b>Godown:</b> Same as above.	Mr. Tanveer Iqbal	Assistant Director- III (MD&MC), DRAP, Islamabad. Mr. Hassan Afzaal, Federal Inspector of Drugs, DRAP, Islamabad.	No	temperature medical devices without cold chain facility.
	M/s Medifar Impex, Suit# 403-4, 4 <sup>th</sup> Floor Mohamdia Plaza College Raod, Rawalpindi.	Farooqi Mrs. NailaTanveer	-do-		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 <b>Godown:</b> 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, 3 <sup>rd</sup> Floor, Majeed Plaza, Bank Road, Rawalpindi. <b>Godown:</b> 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, 3 <sup>rd</sup> Floor Majeed Plaza Bank Road Saddar, Rawalpindi. <b>Godown:</b> Same as above.	Muhammad Saeed.	-do-	No	<b>Approved</b> 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	Approvedfor storage of room temperature medical devices without cold chain facility.

	Rawalpindi.				
	<b>Godown:</b> Same as above.				
93.	M/s JD Professional Healthcare Services (SMC- PVT) Ltd, 3 <sup>rd</sup> Floor, 310/311, Rania Mall, Bank Road, Saddar, Rawalpindi.	Muhammad Junaid Pirzada (Director)	-do-	Yes	Approvedfor 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, 3 <sup>rd</sup> 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	<b>Approved</b> 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	<b>Approved</b> 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	<b>Approved</b> 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	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.
100.	M/s Medi Bridge, Office No. 5, 2 <sup>nd</sup> Floor, Roayal Arcade, Qainchi Ferozepur Road, Lahore.	Mr. Iftikhar Ahmed	-do-	No	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.
101.	M/s Artech Biomed (Pvt) Ltd. 12-A/4, 3 <sup>rd</sup> Floor, Agro Flat, Shadman Market, Shadman 1, Lahore.	Mr. Mumtaz Masood Mrs. Resham Mumtaz	-do-	No	<b>Approved</b> 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	<b>Approved</b> 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	<ul> <li>On the east side of the plot was a rice mill.</li> <li>On the west side of the plot was a vacant plot and main GT Road.</li> <li>On the south side of the plot was a vacant plot.</li> <li>On the north side of the plot was access road and across it was another medical device firm namely Hafiz Pharma.</li> </ul>		
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	<ul> <li>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.</li> <li>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.</li> </ul>
Surrounding	<ul> <li>On the east side of the plot was road.</li> <li>On the west side of the plot was agricultural land.</li> <li>On the south side of the plot was agricultural land.</li> </ul>

	• 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 8<sup>th</sup>October, 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 27<sup>th</sup> 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 27<sup>th</sup> 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.REGISTRATION OF MEDICAL DEVICES FOR EXPORT.

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 <sub>3</sub> , EP/BP)	Sodium Bicarbonate Powder BP/EP in granulated form.650, 720, 750, 1200, 1250grams	
2 <b>HEMOSATE CT</b> (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	
		<b>Part-B (Powder)</b> SodiumNot more than45mmol/1 BicarbonateNot 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	
		Part B (as per BP/EP): SodiumNot 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. CHANGE OF TECHNICAL STAFF OF M/S AMSON VACCINES AND PHARMA (PVT) LTD, ISLAMABAD.

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       1. Mr. Munis Abdulla				
<ul> <li>(CNIC.42201-7571901-7).</li> <li>Mirza Anjum Fahim (CNIC # 24101-7618398-1).</li> <li>Saeed-ur-Rehman (CNIC #16202-0938238-3).</li> </ul>	<ul> <li>(CNIC #42201-9982517-1).</li> <li>Mst. Faiza Naeem <ul> <li>(CNIC # 42201-0540338-0).</li> </ul> </li> <li>Mirza Anjum Fahim <ul> <li>(CNIC # 42101-7618398-1).</li> </ul> </li> <li>Mr. Mudassir Habib Khan <ul> <li>(CNIC # 42000-0528026-1)</li> </ul> </li> <li>Mr. Hammad Bin Kafeel <ul> <li>(CNIC # 42101-1928271-9).</li> </ul> </li> <li>Mr. Tariq M Khan <ul> <li>(CNIC #42301-0725070-1)</li> </ul> </li> </ul>			
Name of Qualified Technical Persons				

Farzan Mazhar
(CNIC # 42101-9526316-1)

- 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. CHANGE OF TECHNICAL PERSON OF M/S NOVATEK PAKISTAN, FAISLABAD.

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	Proposed Technical Person	
Establishment License.		
Miss. Aneela Adeeb, R/o Main	Ms. Wajeeha Ashraf	
Street, Chungi No.8, Lahore Road,	House No.46-P, Street No.4,	
Green Town, Chak No.445/EG,	Mohallah Ameenabad No.1, Tehsil &	
Tehsil Burewala, District Vehari.	District Faisalabad	
CNIC No.366011002417-6	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.	(CEC	Sued Muhammad Zafar Hashmi D), 50/A, Khayaban-e-Shaheen, e 5, DHA, Karachi, CNIC-42301- 592-5.
2.	Mr. Wasif Sajjad, House No. 4E, 11/5, Nazimabad, Karachi CNIC:42101- 2332787-9.	Nazir	Wasif Sajjad, House No. 4E, 11/5, mabad, Karachi CNIC:42101- 787-9.
3.	Mr. Christian Joachim Rainer Hildebrandt, Apartment No.1E-15-12, Quayside Condominlum Sri Tanjung, Penang, 10470, Malaysia.	TheC 11200	Senon Esermann, 521, D-2-1, Cove, Jalan Tanjung Bungah, D, Penang, Malaysia. Christoph Mueller, 1 Tanjong,
4.	Andreas Walde, The Cove D-33A-1, Jalan Tanjung, Bungah 112000 Tanjung Bungah, Penang, Malaysia.	519B-	-21-2, Jalan Tanjung Bungah, 0, 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	Ms Sidra Razzaq
CNIC No: 37405-8322153-9	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<br/>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	Nazar-Ur-Rehman S/O Saeed Ahmed
Zaidi	CNIC No: 35202-1268811-9
CNIC No: 42201-3462739-5	
Previous Technical Staff Details	New Technical Staff Details
Ms Naveen Mazhar Siddiqui	Mr Muhammad Ather Latif Khan
CNIC No: 41303-6831916-4	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</u> <u>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. CHANGE OF BRAND NAME 'LIBIDO' OF M/S HSB INNOVATION IN HEALTH.

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.EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD.

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

Sr	Name of	Name of	Name of Medical	<b>Brief Description</b>	Remarks
No.	Importer	Manufacturer	Device		
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	Hoya-PS AF-1 Hoya Preloaded System Intraocular Lens Class C Shelf Life: 3 Years Model: PC-60R, PY- 60R	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	<b>Approved</b> 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.
		(FSC Singapore Valid Till 07-08- 2020)	Fee submitted: Rs 50,000/-	lens.	
2.	-do-	-do-	Hoya Vivinex iSert Preloaded Intraocular	The HOYA Vivinex™ iSert®	-do-
	(M-11)		Lens Class C Shelf Life: 3 Years Model:XY1 XC1 Fee submitted: Rs	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	
			50,000/-	natural crystalline lens	
3.	-do-	-do-	Hoya iSert Preloaded Intraocular Lens	The HOYA iSert® IOL is intended to	-do-
	(M-11)			be placed into the	

			01 0	1 1 6.1	
			Class C	capsular bag of the	
				eye after	
			Shelf Life: 3 Years	extracapsular	
				cataract removal,	
			Model: 150, 151, 250,	functioning as a	
			251	refractive medium	
				to replace the	
			Fee submitted: Rs	natural crystalline	
			50,000/-	lens	
4.	-do-	-do-	Hoya Vivinex Toric	The HOYA	-do-
			Preloaded Intraocular	Vivinex Toric IOL	
	(M-11)		Lens	is intended to be	
				placed into the	
			Class C	capsular bag of the	
				eye after	
			Shelf Life: 3 Years	extracapsular	
				cataract removal,	
			Model: XY1AT2,	functioning as a	
			XY1AT3, XY1AT4,	refractive medium	
			XY1AT5, XY1AT6,	to replace the	
			XY1AT7, XY1AT8,	natural crystalline	
			XY1AT9	lens	
			Fee submitted: Rs		
			50,000/-		
		1			

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.EXEMPTION FROM INSPECTION OF MANUFACTURER ABOARD.

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

(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.	
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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 30<sup>th</sup> 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 <sup>1/2</sup> 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 <sup>1/2</sup> Round bodied	090759

Silk 1 30 <sup>1/2</sup> 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 11<sup>th</sup> 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 registration 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</u> OF M/S B.BRAUN PAKISTAN (PVT) LIMITED, KARACHI.

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	Name of	Existing Approved	Demanded
		Medical	Manufacturer	Sizes/Codes	Additional Sizes/
		Device			Codes.
1.	MDIR-0000546	Spinocan	Legal	4501144,	4501390
		(Needle For	Manufacturer:	4501195,4501373,	
		Spinal	M/s B.Braun	4501900,	(As per Free Sale
		Anaesthesia)	Melsungen Ag,	4501918,4502140,	Certificate of
			Carl-Braun-	4502906,4503902,4505751,	Germany)
			Strade 1,	4505905,4506014,4507401,	
			34212,	4507754,4507908,4509757,	
			Melsungen,	4509900,4504917,	
			Germany.	4505913,4506090.	
			Manufacturing		
			Site:		
			M/s B.Braun		
			Medical		
			Indusries Sdn.		
			Bhd, Bayan		
			Lepas Free		
			Industrial Zone		
			11900 Penang,		
			Malaysia.		

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</u> <u>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	1m1 2m1 5m1 10m1 20m1	3m1	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. INCREASE IN SHELF LIFE.

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 &	Istanbul Trakya Serbest Bolgesi	
4.0.	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: REGISTRATION AS AN INDENTER UNDER RULE 72(1) OF MEDICAL DEVICES RULES, 2017.

In the 14<sup>th</sup> 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 13<sup>th</sup> 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:**

- 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:			
PROFORM	A INVOICE #:		Origir	1:	
SELLER : BUYER:					
Quantity	Packing	Descriptions	Unit Price C & F	Total Amount	
			City BY AIR/SEA		
Payment : Shipment upto: Negotiation upto:					
From:	6	·	Shipping Marks:		

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	<b>CONDITIONS / INSTRUCTIONS</b>					
<ul> <li>Please comply Bank contracts conditions, &amp; send one complete set of non-negotiable shipping documents to us and as to opener immediately after shipment.</li> <li>Kindly mention product description on each carton.</li> <li>Warranty under Medical Device Rules, 2017. Warranty void if packing is altered</li> </ul>						
I,	, being a person resident in Pakist	an carrying on business (full				
address)		under the				
do hereby g	nameholding valid licence Noissued byissued byind having authority or being authorized by M/s (full address), authorized vide letter Nodated, 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 DE	ETAILS:					
SWIFT CO	ODE:					
Buyers Sigi	gnature For <i>Indentor</i>					

**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 13<sup>th</sup> 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 8<sup>th</sup> 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: <u>VIOLATION OF LABELING REQUIREMENTS ON ACCU-</u> <u>CHEKACTIVE STRIPS OF M/S ROCHE PAKISTAN LIMITED.</u>

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	26002831	M/s Roche Pakistan	2×2×50 strips
	2×50 strips		Limited	
2	Accu-Chek Active	24698723	M/s Roche Pakistan	2×25 strips
	25 strips		Limited	
3	Accu-Chek Active	26000931	M/s Roche Pakistan	2×50 strips
	50 strips		Limited	

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. <u>EXEMPTION FROM INSPECTION ABROAD.</u>

The MDB in its 12<sup>th</sup> 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	Name of Importer	Name of Manufacturer	Name of Medical	Brief
No.	_		Device	Description
1	M/s The Searle	Manufactured By:	Medco® Inject	Sterile
	Company Limited,	M/s Abu Dhabi	Single Use Syringe	Hypodermic
	1 <sup>st</sup> Floor, NICL	Medical Devices Co,	10m1	Syringes
	Building, Abbasi	L.L.C Mussafah City		
	Shaheed Road,	M43 –Block 124, P O	Class B	
	Karachi	Box 30485, Abu Dhabi,		
		UAE	Shelf Life: 3 Years	
	(ELI-00057)			
		(FSC UAE Valid Till		
	Evaluator:	23-01-2019)		
	Muhammad Ayub			
	Naveed	Fee. submitted Rs.		
		25000/-		
<u>2</u>	-do-	Manufacturer/Manufa	Medeco® Inject Re-	Re-Use
		cturing site:	use Prevention	Prevention
	Evaluator:	M/s Abu Dhabi	Syringe	Syringes
	Unum Zia Shamsi	Medical Devices Co,		
		L.L.C	Class B	
		Mussafah City M43 –		
		Plot 124, P O Box	Shelf Life: 3 Years	
		30485, Abu Dhabi,		
	UAE		2/3 ml and 5 ml	
		(FSC UAE Valid Till		
		27-12-2020)		
		Fee submitted		
		Rs.25000/-		

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.<u>ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.</u>

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

			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	Legal	Procleix	A microprocessor-	Approved.
	Systems,	Manufacturer:	Reagent	based, temperature-	<b>11</b>
	Mezzanine	M/s Grifols	Preparation	controlled chamber	
	Floor, Rabbiya	Diagnostic	Incubator (RPI)	that automates the	
	Garden, Block	Solutions Inc., 4560	250	reagent preparation	
	3, MCHS,	Horton St,		steps required for	
	Shaheed-e-	Emeryville, CA	Class A	Procleix assays	
	Millat Road,	94608, USA			
	Karachi	Manufacturing	Life		
	(FI I 00274)	Site:	expectancy: 20		
	(ELI-00274)	M/s 401 Millcreek	Years		
	Evaluator:	Road, Marietta, OH	Fee submitted:		
	Ms. Unum Zia	45750-4304, USA	Rs. 5,000/-		
	Shamsi	(FSC USFDA Valid	10.0,000/-		
	Ciluiioi	Till14-05-2020)			
3.	-do-	Legal	Procleix	An integrated	Approved.
		Manufacturer:	Panther System	nucleic acid testing	<b>* *</b> *
	Evaluator:	M/s Hologic Inc.	, i i i i i i i i i i i i i i i i i i i	system which fully	
	Ms. Unum Zia	10210 Genetic	Class A	automates all steps	
	Shamsi	Center Drive, San		necessary to perform	
		Diego, CA 92121,	Life	Procleix Assys from	
		USA (manufactured	expectancy: 20	sample processing	
		for Grifols	Years	through	
		Diagnostic	The set 1 199 1	amplification,	
		Solutions Inc.)	Fee submitted:	detection and data	
		Manufacturing	Rs. 5,000/-	reduction	
		Site:			
		M/s Neuwiesenstrasse 4,			
		8222 Beringen,			

		Switzerland			
		(FSC US FDA Valid Till 14-05-2020)			
4.	-do- Evaluator: Ms. Hira Bhutto	Legal Manufacturer Lingberg&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	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- <b>Evaluator:</b> 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.

6.	-do- <b>Evaluator:</b> 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 facilities, the mixer is stored inside a bag specially designed for the mixer. 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) <u>Evaluator:</u> 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 <u>Evaluator:</u> 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) <b>Evaluator:</b> Ms. Unum Zia	(FSC Sweden Valid till 25-05-2022)	Micropipettes Plastic, EDTA, 1x100 pcs, Ref:1070039 Boule MPA Micro Pipettes Plastic, EDTA, 10x100 pcs Ref: 1070030	venous sample and direct inserted into the MPA/MCI inlet of medonic CA620/530/Medon ic M-Series and Swelab Alfa automated, hematology analyzers	
	Shamsi		Shelf Life: 36 Months Fee submitted: Rs. 5,000/-		
10.	-do- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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.

	<b>Evaluator:</b> 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 A1 Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e- Iqbal, Karachi. (ELI-00285) <u>Evaluator:</u> 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	<b>Approved</b> . MDB was informed that shortcomings have been received.
15.	-do- <b>Evaluator:</b> 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	<b>Approved</b> . 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 <u>Evaluator:</u> 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

	<b>Evaluator:</b> 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	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	Stability studies.
18.	M/s. A.H Distributors, House No. CB- 708, Lane No. 5, 1st Floor, Peshawar Road, Rawalpindi. ELI-00225 <u>Evaluator:</u> Ms. Unum Zia Shamsi	Manufacturer: M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1 <sup>st</sup> Road, Baolong Industrial Zone, Long gang District, 518116 Shenzhen, Guangdong, China. FSC U.K MHRA issued on 20-04- 2017	months Fee submitted: Rs. 5,000/- Shunmei® TR- Closure Band (Air type) Class A Codes: 629904 629905 629906 629907 Shelf Life: 03 years Fee submitted: Rs. 25,000/-	whole blood or EDTA plasma sample. 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) <b>Evaluator:</b> 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) <u>Evaluator:</u> 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.	<b>Approved</b> subject to fresh Full QA Certificate.
21.	M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055) <u>Evaluator:</u> 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	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) <u>Evaluator</u> : Ms. Unum Zia Shamsi	valid till 21-03-2024) <b>Manufacturer:</b> 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	<b>Approved</b> 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 <sup>™</sup> Urine Bag Class A Size: 200ml, 2000ml	Sterile, disposable urine drainage bag	Approved.

	Yar Khan. ELI-00192 <u>Evaluator:</u> 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 <u>Evaluator:</u> Shahid Muhammad Iqbal	Legal Manufacturer: WIPAK OY, WIPAKTIE 2, FI- 15560 NASTOLA, FINLAND. FSC Finland Issuance: 8 <sup>th</sup> 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- <u>Evaluator:</u> Shahid Muhammad Iqbal	Legal Manufacturer: WIPAK OY, WIPAKTIE 2, FI- 15560 NASTOLA, FINLAND. FSC Finland Issuance: 8 <sup>th</sup> 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- <u>Evaluator:</u> Shahid Muhammad Iqbal	Legal Manufacturer: WIPAK OY, WIPAKTIE 2, FI- 15560, NASTOLA,FINAL ND FSC Finland Issuance: 8 <sup>th</sup> 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 <u>Evaluator:</u> Hafiz Muhammad Asif Iqbal	Legal Manufacturer: M/s. Set Medikal, Sanayi V E tic.A.(Osmangazi Mah. Maresal fevzi cakmak cad. No:18 esenyurtBuyukcekm ece/ 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.<u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

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.	Name and	Manufacture Details	Name of Medical	Brief	Decision
Ν	Addresses of		Device with	Description	
0	Establishment		sizes/Class/Shel		
			f Life		
1.	M/s Johnson	1. Legal	Coated Vicryl TM	A synthetic	The Board only
	& Johnson	Manufacturer:	Plus Antibacterial	absorbable	approved Legal
	(Pvt) Ltd.,	Ethicon LLC	Suture.	sterile surgical	manufacturer M/s
	Office No.806,	475 C Street Los	Class D	suture	Ethicon LLC and
	8th Floor,	Frailes Industrial Park,	Legal	composed of a	its corresponding
	Horizon	Suite 401 Guaynabo,	Manufacturer:	copolymer	manufacturing sites
	Towers, Block	PR USA. 00969	Ethicon LLC	made from 90	and codes and
	3, Scheme 5,		Guaynabo, PR	% glycolide	advised the firm to
	Clifton,	Manufacturing Site:	USA.	and 10 % L-	apply separately for
	Karachi	Ethicon Inc.		lactide.	other legal
		Calle Durango No.	Codes:	Intended for	manufacturer(s)
	(ELI-00154)	2751 Lote Bravo	VCP310H	use in general	and its
		Ciudad Juarez	VCP311H	soft tissue	corresponding
	Evaluator:	Chihuhua Mexico	VCP316H	approximation	manufacturing

Minutes of 15th MDB Meeting (30-12-2019)

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	Ms. Unum Zia	C.P. 32575.	VCP317H	and/or ligation	site(s) and codes.
	Shamsi	(FSC US FDA valid	VCP353H	including	suc(s) and coues.
	GHambi	till 08-04-2021)	VCP358H	microsurgery	
		2. Legal	VCP359H	for vessels than	
		2. Legal Manufacturer:	VCP1428T	2mm diameter	
		Johnson and Johnson	VCP495G	2mm diameter	
		International c/o	ver ibbe		
		European Logistics	Legal		
		Centre, Leonardo Da	Manufacturer:		
		Vincilaan 15, B E-1831	Johnson and		
		Diegem, Belgium	Johnson		
		Manufacturing Sites:	International,		
		Johnson and Johnson	Belgium		
		Medical GmbH,	VCP247H		
		Robert-Koch-Strasse 1,	VCP300H		
		Norderstedt, 22851,	VCP3100H		
		Germany	VCP3110H		
		(FSC UK issued on 24-	VCP320H		
		02-2016)	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/-		
2.	-do-	1. Legal	Articul/EZE <sup>TM</sup>	Intended for	The Board only
		Manufacturer:	(Femoral Head)	use in Primary	approved Legal
	<b>Evaluator:</b>	DePuy International		or Revision	manufacturer M/s
	Ms. Unum Zia	Limited,	Class D	Total Hip	DePuy
	Shamsi	St. Anthony's Road,		Arthroplasty	International
		Leeds LS11 8DT,	Codes:	for the	Limited and its
		United Kingdom.	Legal	provision of	corresponding
		Manufacturing Sites:	Manufacturer:	improved hip	manufacturing sites
		1. Johnson & Johnson	DePuy	joint mobility	and codes and
		Medical (Suzhou)	International	and reduction	advised the firm to
		Ltd.No. 299 Chang	Limited, UK	of joint pain	apply separately for
		Yang Street, Suzhou	1. Articul/EZE		other legal
		Industrial Park,	Femoral Head 12/14		manufacturer(s)
		Suzhou, Jiangsu, 215126, China	Taper 28OD		and its
		215126, China 2. DePuy International	+5		corresponding
		Limited, St. Anthony's	(136512000)		manufacturing
		Road, Leeds LS11	2. Articul/EZE		site(s) and codes.

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r		
	8DT, United	Femoral
	Kingdom.	Head 12/14
		Taper 28OD
	(FSC UK issued on 17-	+1.5
	07-2018)	(136511000)
	-	3. Articul/EZE
	2. Legal	Femoral
	Manufacturer:	Head 12/14
	DePuy (Ireland)	Taper 28OD
	Loughbeg,	+12
	Ringaskiddy, Co.	(136514000)
	Cork, Ireland	4. Articul/EZE
	Manufacturing Site:	Femoral
		Head 12/14
	No. 299 Chang Yang	Taper 32OD
	Street, Suzhou	+1
	Industrial Park,	
	Suzhou, Jiangsu,	(136521000) 5 Articul (EZE
	215126, China	5. Articul/EZE
		Femoral
	(FSC Ireland valid till	Head 12/14
	15-11-2021)	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	<ul> <li>Legal Manufacturer: Depuy Orthopaedics. Inc. 700 Orthopaedic Dr. Warsaw, IN USA 46582</li> <li>Manufacturing sites: <ol> <li>DePuy (Ireland) Loughbeg, Ringaskiddy, Co. Cork, Munster, Ireland</li> </ol> </li> <li>JOHNSON &amp; JOHNSON &amp; JOHNSON MEDICAL (DEPUY- SUZHOU) LTD. No. 299, Changyang Street, Suzhou Industrial Park, Suzhou</li> <li>CREAMTEC GmbH Medical Products Division. CreamTec-Weg 1 MARKTREDWI TZ, Bayern GERMANY D- 95615</li> <li>GREATBATCH MEDICAL 4545 Kroemer Rd, Fort Wayne, IN USA</li> </ul>	Pinnacle® Hip System Class D Codes: 121720044PINN ACLE BANTAM ACET CUP 44MM 10 years 121720046PINN ACLE BANTAM ACET CUP 46MM 10 years 121720046PINN ACLE BANTAM ACET CUP 46MM 10 years 121720048PINN ACLE MULTIHOLE II CUP 48MM 10 years 121720050PINN ACLE 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	MULTIHOLE II	
	CUP 56MM 10	
5. Haven	years	
Manufacturing.	121720058	
6935 N State	PINNAC	
Road 1 OSSIAN,	LE	
IN USA 46777	MULTIHOLE II	
	CUP 58MM 10	
6. NG Instruments.	years	
4643 N State	121720060	
	PINNAC	
Road 15,		
Warsaw, IN USA	LE	
46582	MULTIHOLE II	
	CUP 60MM 10	
7. DEPUY	years	
ORTHOPAEDIC	121720500	
S, INC. 325	PINN	
PARAMOUNT	CAN BONE	
DR.	SCREW	
RAYNHAM,	6.5MMX20MM	
MA USA, 02767	10 years	
,,	121722048	
8. NORWOOD	PINNAC	
MEDICAL 2122	LE SECTOR II	
Winners Circle,	CUP 48MM 10	
Dayton, OH USA	years	
45404		
45404	121722050	
	PINNAC	
9. PARAGON	LE SECTOR II	
MEDICAL, INC.	CUP 50MM 10	
8 Matchett Dr.	years	
PIERCETON, IN	121722052	
USA 46562	PINNAC	
	LE SECTOR II	
10. SYMMETRY	CUP 52MM 10	
MEDICAL	years	
MANUFACTUR	121722054	
ING INC. 486	PINNAC	
west 350 North	LE SECTOR II	
WARSAW, IN	CUP 54MM 10	
USA 46582	years	
	121722056	
11. PERRYMAN	PINNAC	
COMPANY. 149	LE SECTOR II	
S Johnson Rd	CUP 56MM 10	
,	years	
USA 15342	121722058	
	PINNAC	
12. COORSTEK	LE SECTOR II	
MEDICAL LLC	CUP 58MM 10	
DAYTON MFG.	years	
811 Northwoods	121722060	

 		 -
Blvd Vandalia,	PINNAC	
OH USA 45377	LE SECTOR II	
	CUP 60MM 10	
(FSC US FDA valid	years	
till 21-05-2021)	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 28IDX500D	
	5 years	
	121832752	
	PINN	
	LNR CON +4	
	10D 32IDX52OD	
	5 years	
	121832754	
	PINN	
	LNR CON +4	
1	1	•

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
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LNR CON +4
10D 36IDX60OD
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121881752
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540DX36ID 5
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32ID X 48OD 5
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CER INSERT
32ID X 50OD 5
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121882752
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INSRT 520DX22ID 5
52ODX32ID 5
years
121883744
PINN DELTA CER
INSRT
44ODX28ID 5
years
121883746
PINN
DELTA CER
INSRT
460DX28ID 5
years
121883748
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28IDX56OD 5	
years	
121928158	
PINN	
MAR +4 10D	
28IDX58OD 5	
years	
121928160	
PINN	
MAR +4 10D	
28IDX600D 5	
years	
121932148	
PINN	
MAR +4 10D	
32IDX48OD 5	
years	
121932150	
PINN	
MAR +4 10D	
32IDX500D 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	
32IDX580D 5	
years	
121932160	

PINN
MAR +4 10D
32IDX600D 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
130327000

ARTICU	
L/EZE BALL	
22.225+4 NK 5	
years	
136530000	
ARTICU	
L/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	
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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		
4.	-do- <b>Evaluator:</b> 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)	50,000/- Webster fixed diagnostic catheter (4F,5F, 6F Electrophysiology catheter) Class D Codes: 37S94R 37S95R 37C53R 37C03R 37C03R 37U00R 37G68R 37C03R 37D00R 37D08R 37D08R 37D03R 37D03R 37D03R 37D38R 37D38R 37D38R 37D58R 37D58R 37D55R 37D55R 37D55R 37T03R	Indicated for electrophysiolo gical mapping of cardiac structures i.e stimulation and recording only	Approved.
			Shelf Life: 3 years Fee submitted: Rs. 50,000/-		
5.	-do- <b>Evaluator:</b> 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	Webster® Duo- Decapolar Electrophysiology Catheter (Deflectable Tip Electrode Catheter) Class D Code: D728260RT Shelf life: 36 months Fee submitted: Rs. 50,000/-	Indicated for electrophysiolo gical 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.
		(FSC US FDA valid 21-02-2021)			

6.	-do-	Legal Manufacturer:	DecaNav <sup>TM</sup>	Indicated for	Approved.
		Biosense Webster, Inc,	Electrophysiology	electrophysiolo	
	<b>Evaluator:</b>	33 Technology Drive	Catheter	gical mapping	
	Ms. Unum Zia	Irvine, CA USA,	Class D	of cardiac	
	Shamsi	92618.	Codes:	structure i.e,	
		Manufacturing sites:	R7D282CT	recording and	
		1. Biosense Webster,	R7F282CT	stimulation,	
		Inc, 15715 Arrow	01 107 10 1	including in	
		Hwy, Irwindale, CA	Shelf Life: 1 year	the coronary	
		USA. 91706.	Fee submitted:	sinus. Also used with	
		2. Biosense Webster,	Rs. 50,000/-	compatible	
		Inc, Circuito Interior Norte, No. 1820		Carto® 3 EP	
		Parque Industrial		navigation	
		Salvarcar Juarez,		systems to	
		Chihuahua Mexico		provide	
		32574		catheter tip	
				location	
		(FSC US FDA valid		information.	
		21-02-2021)			
7.	-do-	Legal Manufacturer:	SmartAblate™	Designed for	Approved.
	<b>T</b>	Biosense Webster, Inc,	Irrigation Tubing	use with the	
	Evaluator:	15715 Arrow Hwy,	Set	SMARTABL	
	Ms. Unum Zia Shamsi	Irwindale, CA USA. 91706.	Class B Code: SAT001	ATE <sup>™</sup> Irrigation	
	Shamsi	91706.	Coue. SATOOT	Pump to	
		Manufacturing site:	Shelf Life: 1 Year	deliver	
		Venusa de Mexico S.	onen Ene. 1 1 eur	irrigation	
		de. R.L de C.V Calle	Fee submitted:	solution at	
		Hertz 1525 Parque	Rs. 25,000/-	specified flow	
		Industrial J. Bermudez	,	rates to	
		Ciudad Juarez		CELSIUS®	
		Chihuahua Mexico		THERMOCO	
		32470		OL® Catheter,	
				NAVISTAR®	
		(FSC US FDA valid		THERMOCO	
		till 13-01-2021)		OL® Cathotor or	
				Catheter, or other irrigated	
				devices for	
				cooling	
				purposes.	
8.	-do-	Legal Manufacturer:	ThemoCool®	Indicated for	Approved.
		Biosense Webster, Inc,	SmartTouch™	catheter-based	
	<b>Evaluator:</b>	33 Technology Drive	Catheter	cardiac	
	Ms. Unum Zia	Irvine, CA USA,	Class D	electrophysiolo	
	Shamsi	92618.	Codes:	gical mapping	
			D132701	(stimulating	
		Manufacturing sites:	D132702	and recording)	
		1. Biosense Webster,	D132703 D132704	and, when used in	
		Inc, 15715 Arrow Hwy, Irwindale, CA	D132704 D132705	conjunction	
		11wy, 11willuale, CA	D152705	conjunction	

		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- <b>Evaluator:</b> 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 electrophysiolo gical procedures. It provides information about the electrical activity of the heart and about catheter location during the procedure	Approved.
10.	-do- <b>Evaluator:</b> 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 BNI35BBCT BNI35BDH BNI35BDCT BNI35BFCT BNI35DFH BNI35DDCT BNI35DDH BNI35DJH BNI35DJH BNI35DJH BNI35FFCT BNI35FFH BNI35FFH BNI35FFH BNI35FJH BNI35JJCT BNI35JJH D131501 D131502	Indicated for catheter-based cardiac electrophysiolo gical mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.	Approved.

11.	-do-	1. Legal	D131801 D131802 D131803 D131804 Shelf Life: 3 years Fee submitted: Rs. 50,000/- Monocryl ™	Sterile,	The Board only
	Evaluator: Ms. Unum Zia Shamsi	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)	Poliglecaprone 25 Suture Class D Codes: Legal Manufacturer: Ethicon LLC, Guaynabo, PR USA. W3204 W3205 W3206 W3650 W3758 W3758 W3759 Y493G Legal Manufacturer: Johnson and Johnson International, Belgium W3204 W3205 W3206 W3650 W3758 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/-	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.	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.

Evaluator: Ms. Unum Zia ShamsiEfficient LLC 475 C Street Los Prailes Industrial Park, Suite 401 Guaynabo, PE USA. 00960 PH USA. 00960 Class D Manufacturing Site: Ethicon LLC, Highway 183 Km. 8.3 San Lorenzo. PR USA 00754Symmetric PDS/PP1A101 SXPP1A100 SXPP1A201 Diverset, SXPP1A301 Undicated for SXPP1A400 SXPP1A401 SXPP1A405 SXPP1A400 SXPP1A406 SXPP1A408 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A433 SXPP1A445 SXPP1A442 <br< th=""><th>12.</th><th>-do-</th><th>Legal Manufacturer:</th><th>Stratafix™</th><th>An anti-</th><th>Approved.</th></br<>	12.	-do-	Legal Manufacturer:	Stratafix™	An anti-	Approved.
Evaluator: Ms. Unum Zia Shamsi475 C Street Los Fraies Industrial Park, ShamsiPDS™ Plus Knoless Tissue Class D Odes: absorbable device(polydioxenon c) non filament synthetic deviceManufacturing Site: Ethicon LLC, Highway 183 Km. 8.3 San Lorenzo. PR USA 00754SXPP1A100 SXPP1A200 pely(p- sXPP1A301 general soft sXPP1A400 sXPP1A400 sXPP1A400 sXPP1A400 sXPP1A400 sXPP1A400 sXPP1A400 sXPP1A401 sXPP1A401 sXPP1A404 sXPP1A404 sXPP1A406 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A408 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A406 SXPP1A408 SXPP1A406 SXPP1A433 SXPP1A436 SXPP1A436 SXPP1A436 SXPP1A438 SXPP1A434 SXPP1A444 SXPP1A444 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A446 SXPP1A448 SXPP1A448 SXPP1A446 SXPP1A446 SXPP1A446 SXPP1A448 SXPP1A446 SXPP1A448 SXPP1A446 SXPP1A448 SXPP1A446 SXPP1A448 SXPP1A448 SXPP1A446 SXPP1A448 SXPP1A448 SXPP1A448 SXPP1A446 SXPP1A446 SX						
Ms. Unum Zia Shamsi Prailes Industrial Park, Suite 401 Guaynabo, PR USA. 00960 Manufacturing Site: Ethicon LLC, Highway 183 Km. 8.3 San Lorenzo. PR USA 00754 (FSC US FDA valid till 18-06-2020) SXPP1A201 SXPP1A300 SXPP1A400 SXPP1A400 SXPP1A400 SXPP1A404 SXPP1A404 SXPP1A404 SXPP1A405 SXPP1A405 SXPP1A405 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A438 SXPP1A434 SXPP1A444 SXPP1A444 SXPP1A442 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444 SXPP1A444		Evaluator:				
ShamsiSuite 401 Guaynabo, PR USA. 00969Control Device Class D absorbable deviceManufacturing Site: Ethicon LLC, Highway 183 Km, 8.3 San Lorenzo. PR USA 00754SXPP1A100 SXPP1A201 gloxet, SXPP1A201 gloxet after an absorbable dioxanone).(FSC US FDA valid till 18-06-2020)SXPP1A301 SXPP1A400 SXPP1A400 SXPP1A400 SXPP1A400 SXPP1A400 approximation SXPP1A401 approximation SXPP1A404 sypropriateSXPP1A401 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A410 SXPP1A410 SXPP1A410 SXPP1A418 SXPP1A443 SXPP1A445 SXPP1A445 SXPP1A445 SXPP1A446					· ·	
PR USA. 00969 Manufacturing Site: Ethicon LLC, Nighway 183 Km, 8.3 San Lorenzo. PR USA 00754 (FSC US FDA valid till 18-06-2020) SXPP1A201 SXPP1A201 GFSC US FDA valid till 18-06-2020) SXPP1A400 SXPP1A402 SXPP1A402 SXPP1A403 SXPP1A404 SXPP1A404 SXPP1A404 SXPP1A405 SXPP1A405 SXPP1A407 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A409 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A409 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A410 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440					,	
Manufacturing Site: Ethicon LLC, Highway 183 Km, 8.3 San Lorenzo, PR USA 00754Codes: SXPP1A200 poly(p- dioxanone). SXPP1A201 dioxanone). GXPP1A301 general soft till 18-06-2020)Codes: SXPP1A301 general soft strend SXPP1A400 approximation SXPP1A400 approximation SXPP1A400 approximation SXPP1A400 appropriate SXPP1A400 SXPP1A400 strend SXPP1A400 SXPP1A400 SXPP1A400 SXPP1A400 SXPP1A401 SXPP1A402 SXPP1A403 SXPP1A404 SXPP1A405 SXPP1A405 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A410 SXPP1A420 SXPP1A410 SXPP1A420 SXPP1A411 SXPP1A420 SXPP1A435 SXPP1A435 SXPP1A435 SXPP1A436 SXPP1A433 SXPP1A433 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A446		onumbr			<b>J</b>	
Ethicon LL C, Highway 183 Km. 8.3 San Lorenzo. PR USA 00754SXPP1A100 SXPP1A200 poly(p- dioxanone).(FSC US FDA valid till 18-06-2020)SXPP1A301 SXPP1A400 SXPP1A400 SXPP1A401 SXPP1A402 SXPP1A403 suture is SXPP1A403 SXPP1A404 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A406 SXPP1A409 SXPP1A406 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A419 SXPP1A419 SXPP1A418 SXPP1A436 SXPP1A436 SXPP1A412 SXPP1A412 SXPP1A412 SXPP1A412 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A440 SXPP1A446						
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San Lorenzo. PR USA 00754SXPP1A200 SXPP1A201poly(p- dioxanone). Indicated for general soft tissue(FSC US FDA valid till 18-06-2020)SXPP1A300 SXPP1A400 SXPP1A401 SXPP1A403 SXPP1A403 sture is SXPP1A403 SXPP1A404 SXPP1A404 SXPP1A405 SXPP1A405 SXPP1A406 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A406 SXPP1A407 SXPP1A406 SXPP1A408 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A408 SXPP1A410 SXPP1A410 SXPP1A410 SXPP1A414 SXPP1A414 SXPP1A414 SXPP1A420 SXPP1A433 SXPP1A434 SXPP1A434 SXPP1A420 SXPP1A420 SXPP1A420 SXPP1A433 SXPP1A434 SXPP1A434 SXPP1A421 SXPP1A434 SXPP1A446			,			
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(FSC US FDA valid till 18-06-2020)SXPP1A301 SXPP1A400 SXPP1A401 SXPP1A402 an absorbable SXPP1A403 suture is SXPP1A404 SXPP1A404 SXPP1A406 SXPP1A406 SXPP1A407 SXPP1A407 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A408 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A409 SXPP1A400 SXPP1A410 SXPP1A440 SXPP1A444 SXPP1A445 SXPP1A445 SXPP1A445 SXPP1A446						
till 18-06-2020)       SXPP1A302       tissue         SXPP1A401       where use of         SXPP1A402       an absorbable         SXPP1A403       suture is         SXPP1A404       appropriate         SXPP1A405       suture is         SXPP1A406       SXPP1A406         SXPP1A407       SXPP1A408         SXPP1A408       SXPP1A409         SXPP1A409       SXPP1A409         SXPP1A203       SXPP1A409         SXPP1A306       SXPP1A304         SXPP1A410       SXPP1A304         SXPP1A419       SXPP1A430         SXPP1A436       SXPP1A430         SXPP1A435       SXPP1A430         SXPP1A445       SXPP1A430         SXPP1A445       SXPP1A430         SXPP1A445       SXPP1A445         SXPP1A445       SXPP1A445         SXPP1A445       SXPP1A445         SXPP1A420       SXPP1A445         SXPP1A445       SXPP1A445         SXPP1A445       SXPP1A445         SXPP1A426       SXPP1A426         SXPP1A426       SXPP1A426         SXPP1A440       SXPP1A440         SXPP1A440       SXPP1A440         SXPP1A440       SXPP1A446			(FSC US FDA valid		general soft	
SXPP1A400         approximation           SXPP1A401         where use of           an absorbable         sxPP1A402           SXPP1A403         suture is           sXPP1A405         sypp1A405           SXPP1A406         sypp1A406           SXPP1A406         sypp1A407           SXPP1A407         sypp1A408           SXPP1A408         sypp1A408           SXPP1A409         sypp1A408           SXPP1A409         sypp1A408           SXPP1A409         sypp1A408           SXPP1A409         sypp1A203           SXPP1A203         sypp1A306           SXPP1A306         sypp1A419           SXPP1A306         sypp1A435           SXPP1A436         sypp1A443           SXPP1A436         sypp1A443           SXPP1A444         sypp1A443           SXPP1A303         sypp1A443           SXPP1A304         sypp1A443           SXPP1A305         sypp1A430           SXPP1A430         sypp1A441           SXPP1A433         sypp1A441           SXPP1A433         sypp1A441           SXPP1A440         sypp1A446           SXPP1A440         sypp1A446           SXPP1A446         sypp1A446			•	SXPP1A302		
SXPP1A401       where use of         SXPP1A402       an absorbable         SXPP1A403       suture is         appropriate       SXPP1A406         SXPP1A406       SXPP1A406         SXPP1A407       SXPP1A406         SXPP1A408       SXPP1A407         SXPP1A409       SXPP1A408         SXPP1A409       SXPP1A409         SXPP1A409       SXPP1A400         SXPP1A203       SXPP1A203         SXPP1A304       SXPP1A304         SXPP1A304       SXPP1A306         SXPP1A410       SXPP1A419         SXPP1A435       SXPP1A435         SXPP1A435       SXPP1A433         SXPP1A444       SXPP1A444         SXPP1A303       SXPP1A204         SXPP1A305       SXPP1A305         SXPP1A305       SXPP1A305         SXPP1A305       SXPP1A412         SXPP1A426       SXPP1A433         SXPP1A446       SXPP1A446			,	SXPP1A400	approximation	
SXPP1A403       suture is         SXPP1A404       appropriate         SXPP1A405       SXPP1A406         SXPP1A407       SXPP1A407         SXPP1A408       SXPP1A409         SXPP1A409       SXPP1A400         SXPP1A203       SXPP1A203         SXPP1A306       SXPP1A304         SXPP1A306       SXPP1A419         SXPP1A435       SXPP1A435         SXPP1A435       SXPP1A436         SXPP1A436       SXPP1A436         SXPP1A435       SXPP1A436         SXPP1A436       SXPP1A437         SXPP1A435       SXPP1A436         SXPP1A435       SXPP1A436         SXPP1A430       SXPP1A444         SXPP1A433       SXPP1A434         SXPP1A434       SXPP1A434         SXPP1A434       SXPP1A446				SXPP1A401		
SXPP1A404       appropriate         SXPP1A405       SXPP1A405         SXPP1A406       SXPP1A407         SXPP1A409       SXPP1A409         SXPP1A203       SXPP1A203         SXPP1A306       SXPP1A306         SXPP1A410       SXPP1A419         SXPP1A419       SXPP1A306         SXPP1A419       SXPP1A435         SXPP1A435       SXPP1A435         SXPP1A443       SXPP1A443         SXPP1A444       SXPP1A443         SXPP1A303       SXPP1A445         SXPP1A303       SXPP1A436         SXPP1A303       SXPP1A445         SXPP1A418       SXPP1A426         SXPP1A444       SXPP1A446				SXPP1A402	an absorbable	
SXPP1A405       A         SXPP1A406       SXPP1A406         SXPP1A407       SXPP1A407         SXPP1A408       SXPP1A409         SXPP1A409       SXPP1A203         SXPP1A203       SXPP1A304         SXPP1A304       SXPP1A306         SXPP1A410       SXPP1A419         SXPP1A420       SXPP1A435         SXPP1A436       SXPP1A434         SXPP1A443       SXPP1A443         SXPP1A4445       SXPP1A4445         SXPP1A202       SXPP1A303         SXPP1A305       SXPP1A412         SXPP1A412       SXPP1A425         SXPP1A441       SXPP1A444         SXPP1A440       SXPP1A440         SXPP1A440       SXPP1A440				SXPP1A403	suture is	
SXPP1A406         SXPP1A407         SXPP1A408         SXPP1A409         SXPP1A409         SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A437         SXPP1A444         SXPP1A430         SXPP1A433         SXPP1A444         SXPP1A202         SXPP1A202         SXPP1A303         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440				SXPP1A404	appropriate	
SXPP1A407         SXPP1A408         SXPP1A409         SXPP1A400         SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A304         SXPP1A419         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A438         SXPP1A438         SXPP1A430         SXPP1A444         SXPP1A444         SXPP1A202         SXPP1A202         SXPP1A204         SXPP1A305         SXPP1A305         SXPP1A412         SXPP1A426         SXPP1A426         SXPP1A433         SXPP1A442         SXPP1A4442				SXPP1A405		
SXPP1A408         SXPP1A409         SXPP1A400         SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A435         SXPP1A435         SXPP1A435         SXPP1A436         SXPP1A435         SXPP1A436         SXPP1A435         SXPP1A436         SXPP1A435         SXPP1A436         SXPP1A444         SXPP1A202         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A442         SXPP1A442				SXPP1A406		
SXPP1A409         SXPP1A203         SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A435         SXPP1A436         SXPP1A435         SXPP1A444         SXPP1A444         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A430         SXPP1A420         SXPP1A444         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A418         SXPP1A433         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A446				SXPP1A407		
SXPP1A410         SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A436         SXPP1A436         SXPP1A443         SXPP1A443         SXPP1A445         SXPP1A445         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A303         SXPP1A418         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A203         SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A436         SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A205         SXPP1A204         SXPP1A305         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A441         SXPP1A440         SXPP1A440						
SXPP1A205         SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A445         SXPP1A202         SXPP1A303         SXPP1A303         SXPP1A305         SXPP1A305         SXPP1A412         SXPP1A426         SXPP1A433         SXPP1A441         SXPP1A441         SXPP1A441         SXPP1A446						
SXPP1A304         SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A436         SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A412         SXPP1A426         SXPP1A426         SXPP1A426         SXPP1A426         SXPP1A441         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A306         SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A436         SXPP1A443         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A445         SXPP1A420         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A412         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A446						
SXPP1A419         SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A43         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A420         SXPP1A435         SXPP1A436         SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A445         SXPP1A402         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A412         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A441         SXPP1A440         SXPP1A440         SXPP1A446						
SXPP1A435         SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A444         SXPP1A446						
SXPP1A436         SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A443         SXPP1A444         SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A441         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A444         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A4440         SXPP1A440         SXPP1A441         SXPP1A446						
SXPP1A445         SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A412         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A446						
SXPP1A202         SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A441         SXPP1A441         SXPP1A446						
SXPP1A204         SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A441         SXPP1A441         SXPP1A442         SXPP1A446						
SXPP1A303         SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A446						
SXPP1A305         SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A440         SXPP1A442         SXPP1A446						
SXPP1A412         SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A440         SXPP1A441         SXPP1A442         SXPP1A446						
SXPP1A418         SXPP1A425         SXPP1A426         SXPP1A433         SXPP1A434         SXPP1A440         SXPP1A441         SXPP1A442         SXPP1A446						
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			SXPP1A415		
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			SXPP1A410		
			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:		
10	1	1 T 134 0	Rs. 50,000/-	0, 1	
13.	-do-	1. Legal Manufacturer:	Ethibond Excel <sup>TM</sup>	Sterile,	The Board only
	E dura	Ethicon, LLC. 475 C	polyester suture	braided,	approved Legal
	Evaluator:	Street, Los Frailes	Class D	polybutylate	manufacturer M/s
	Ms. Unum Zia	-	Codes:	coated	Ethicon LLC and
	Shamsi	401 Guaynabo, Puerto	Legal Manufacturer:	polyester	its corresponding
		Rico		synthetic non absorbable	manufacturing sites
		00969, USA Manufacturing Site:	Ethicon LLC, Guaynabo, PR	surgical suture.	and codes and
		Ethicon, INC. Calle	USA.	Indicated for	advised the firm to
		Durango No. 2751	X893G	use in general	apply separately for
		LOTE BRAVO	X4843G	soft tissue	other legal
		CIUDAD JUAREZ	X4B37G	approximation	manufacturer(s)
		Chihuahua MEXICO	X4B77G	and/or	and its
		C.P. 32575	X4D770 X6977M	ligation,	corresponding
			X582H	including use	manufacturing
		(FSC USFDA valid till	X905G	in	site(s) and codes.
		08-04-2021)	X884G	cardiovascular,	
		,	X894G	ophthalmic	
		2. Legal Manufacturer:	X6757G	and	
		Ethicon, LLC	X6761G	neurosurgicalp	
		Highway 183 km 8.3,	X31059H	rocedures.	
		/	•		

	San Lorenzo, Puerto	X32071H	
	Rico 00754, USA	X31083H	
	Manufacturing Site:	W6191	
	Ethicon, LLC	W10B52	
	Highway 183 km 8.3,	W10B54	
	San Lorenzo, Puerto	W10B55	
	Rico 00754, USA	W10B55 W10B72	
	KICO 00754, USA		
		W10B77	
	(FSC USFDA valid till	W4843	
	03-04-2021)	W4846	
		W6552	
		W6767	
		W6935	
		W6936	
		W6937	
		W6977	
		W893	
		X523H	
		X937H	
		10X42N	
		10X82N	
		PXX41N	
		PXX43N	
		PXX76N	
		PXX80N	
		10X86N	
		Legal	
		Manufacturer:	
		Ethicon LLC,	
		,	
		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	
LI	L	(notanizer) that	

Evaluator: Ms. Unum ZiaManufacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969(Polyglactin 910) Suturesynthetic absorbable surgical sutureapproved Le manufacturing si and codes a advised the firm apply separately otherManufacturing Site: Ethicon Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.P. 32575.Codes: Ethicon LLC, Itation USA.manufacturer: and 10% L- lactide.advised the firm apply separately otherManufacturer: Cliudad Juarez C.P. 32575.USA.use in general and / or ligation, W9211including use manufacturing site(s) and codes.2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, BelgiumW9422 W9552surgery, matesW9522diameter.W9552diameter.				are manufacture 1		
14.       -do- Evaluator: Ms. Unum Zia Shamsi       Legal Manufacturer Ethicon, LLC. Highway 183 Km. 8.3 Shamsi       Legal Manufacturer Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       Sterile, surgical Stainless Steel Suture       Approved.         Manufacturing Site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       Class C       suture for use in abdominal codes: wound closure, hermia repair, M651G       Approved.         15.       -do- Evaluator: Ms. Unum Zia Shamsi       1. Legal Manufacturer: Hiticon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       M650G Months       sterile procedures including corelage and tendon repair. Fee submitted: Rs 50,000/-       The Board o approved Le synthetic Rs 50,000/-         15.       -do- Evaluator: Ms. Unum Zia Shamsi       1. Legal Manufacturer Wite 401 Guayabo, PR USA, 00969 Manufacturer Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chibuntua Mexico C.P. 3257S.       Sterile surgical suture USA, USA, Difference C.P. 3257S.       The Board o approved Le surgical suture Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chibuntua Mexico C.P. 3257S.       The Board o advised the firm manufacturer(s) and codes a advised the firm apply separately other le surgery, W9105 W9105 Bigation, Neveral Advised the firm apply separately other duracturing si and codes a advised the firm apply separately other le surgery, W9221 including use W391         2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE 1831 Diegem, Belgium W9521T       Sterile W9522T       Sterile W9522T       Sterile w9522T <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>						
14.     -do-     Legal Manufacturer Ethicon, LLC.     Surgical Stainless Steel Suture     Sterile, surgical non absorbable stainless steel stuture for use in abdominal wound closure, Manufacturing Site:     Approved.       Evaluator: Ms. Unum Zia Shamsi     Legal Manufacturer Ethicon, LLC.     Surgical Stainless Steel Suture     Sterile, surgical non absorbable stainless steel un abdominal wound closure, M650G     Approved.       Manufacturing Site: Highway 183 Km. 8.3 San Lorenzo, PR USA 00754     Class C     sternal closure and othopaedic procedures in cluding cerclage and tendon repair.     The Board o approved Le manufacturer       15.     -do-     1. Legal Manufacturer: Shelf Life: 60 (FSC US FDA valid iil 08-04-2021)     VieryI <sup>TM</sup> (Polyglactin 910) Synthetic absorbable surgical suture Surgical suture Surgical suture Surgical suture Cooposed of co-polymer Trailes Industrial Park, Suite 401 Guaynabo, PR USA, 00969     Codes: Cales: Dawnabacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA, 00969     Codes: Manufacturer Guaynabo, PR USA, 00969     The Board o approved Le manufacturer M advised the firm apply separately other     advised the firm apply separately other       2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilan 15, B E 1831 Diegem, Belgium     W9391 W9521T     in ophthalmic W9522T     or manufacturer.				5		
Id.       -do- Evaluator: Bislamsi       Legal Manufacturer Ethicon, LLC. Highway 183 Km. 8.3 Shamsi       Fee submitted: Rs. 50,000/- Steel Suture       Sterile, surgical stainless steel suture       Approved.         14.       -do- Evaluator: Ms. Junum Zia Shamsi       Legal Manufacturer Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       Class C       Sterile, surgical suture for use in abdominal wound closure, hermia repair, M651G       Approved.         15.       -do- Evaluator: Ms. Unum Zia Shamsi       1. Legal Manufacturer: Ethicon, LLC       Woodo (PSC US FDA valid til 08-04-2021)       M400G       othopaedic procedures including cerclage and til 08-04-2021)       The Board or approved Le manufacturer: Ethicon LLC         15.       -do- Evaluator: Ms. Unum Zia Shamsi       1. Legal Manufacturer: Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00069       VieryI <sup>MM</sup> Suture       Sterile synthetic absorbable synthetic absorbable surgical suture absorbable surgical suture surgical suture absorbable surgical suture Shamsi       The Board or approved Le manufacturer: Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chibuhua Mexico C.P. 32575. (FSC US FDA valid til 08-04-2021)       VieryI <sup>M</sup> StatG USA. USA. USA. USA. USA. USA. USA. USA.						
Id.     -do- Evaluator: Ms. Unum Zia Shamsi     Legal Manufacturer Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754     Sterile Class C     Sterile, surgical non absorbable suture for use in abdominal Codes: Wound closure, hernia repair, Stansi     Approved.       14.     -do- Evaluator: Ms. Unum Zia Shamsi     Manufacturing Site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754     Class C     suture for use in abdominal Codes: Wound closure, hernia repair, Stand Lorenzo, PR USA 00754     Ad00G       15.     -do- Evaluator: Ms. Unum Zia Shamsi     1. Legal Manufacturer: Ethicon LLC     VicryI <sup>TM</sup> Pre submitted: Rs 50,000/-     Sterile synthetic absorbable suture for use in abdominal codes: Wound closure, M650G     The Board o approved Le manufacturer M Ethicon LLC       15.     -do- Evaluator: Ms. Unum Zia Shamsi     1. Legal Manufacturer: Citicon LLC     VicryI <sup>TM</sup> Class D     Sterile synthetic absorbable sutire 401 Guaynabo, PR USA. 00969     Sterile Manufacturer: Class D     The Board o approved Le manufacturer M Ethicon LLC       16.     C.do- Z751 Lote Bravo Ciudad Juarez Chibuhua Mexico C.P. 32575, Class D     Class D     corpolymer made from ad its corresponding manufacturer(s) and doter la advised the firm apply separately other la advised the firm apply separately diameter.       10.     2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilan 15, B E1831 Diegem, Belgium     W95107 and W95227     anastomosis mastomosis W95107						
14.       -do- Evaluator: Ms. Unum Zia Shamsi       Legal Manufacturer Ethicon, LLC. Manufacturing Site: Ethicon, LLC. Manufacturing Site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       Sterile, surgical Steel Stuture in abdominal codes: Mo51G       Approved.         15.       -do- Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       Class C       strail closure procedures in cluding cerclage and tendon repair.       The Board o approved Le manufacturer M Shelf Life: 60         15.       -do- Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       M400G       othopaedic procedures including cerclage and tendon repair.         15.       -do- Highway 183 Km. 8.3 San Lorenzo, PR USA 00754       M400G       othopaedic procedures including cerclage and tendon repair.         15.       -do- Highway 183 Km. 8.3 Shamsi       1. Legal Manufacturer: Ethicon LLC       VicryI <sup>TM</sup> Suite 401 Guaynabo, PR USA. 00669       Sterile Manufacturer Suite 401 Guaynabo, PR USA. 00969       Sterile Manufacturer Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.P. 32575.       Class D Codes: USA.       Sterile surgical suture thicon ILC. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.P. 32575.       J442H Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issued       USA.       and codes a advised the firm anufacturing site(s) and codes.         V9511T       microsurgery W9522T       W9510T       and manufacturing site(s) and codes.						
Evaluator: Ms. Unum Zia ShamsiEthicon, LLC. Highway 183 Km 8.3 San Lorenzo, PR USA 00754Steel Suturenon absorbable stainless steel suture for use in abdominal Wo650G hernia repair, M651G made duited till 08-04-2021)Steel Suturenon absorbable stainless steel suture for use in abdominal Wo650G procedures including synthetic absorbable synthetic synthetic approved Legal Manufacturer: Ethicon LLC Highway 183 Km 8.3 San Lorenzo, PR USA 00754Steel VieryIM MonthsThe Board on approved Legal and cereclage and tendon repair. Fee submitted: Rs. 50,000/-15do- H. Legal Ms. Unum Zia Shamsi1. Legal Manufacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA, 00969 DA 0969 PR USA, 00969 C.2751 Lote Bravo C.751 Lote Bravo C.P. 32575. (FSC US FDA valid till 08-04-2021)Sterile Class D Codes: Legal Manufacturer: and 10% L- lactide. Intended for USA.The Board on approved Legal and codes a advised the firm and/corresponding manufacturer(s) and corresponding manufacturer(s) including use in ophthalmic W9421 W9391 in ophthalmic W9423 W92211 including use including use <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>						
Evaluator: Ms. Unum Zia ShamsiHighway 183 Km. 8.3 San Lorenzo, PR USA 00754Class Cstainless steel suture for use in abdominal wound closure, hernia repair, Procedures including procedures including (FSC US FDA valid till 08-04-2021)Class Cstainless steel suture for use nemia repair, Procedures including cerclage and tendon repair.15do- Highway 183 Km. 8.3 San Lorenzo, PR USA 00754M400G Monthsothopaedic procedures including cerclage and tendon repair.15do- Highway 183 Km. 8.3 San Lorenzo, PR USA 00754I. Legal MonthsMonthsThe Board o approved Le supical suture supical suture composed of manufacturer. M Suite 401 Guynabo, PR USA. 00699Sterile Manufacturer: Legal USA.The Board o approved Le supical suture composed of manufacturer. M absorbable surgical suture composed of manufacturing site titic on Inc. Calle Durango No. 2.751 Lote Bravo Cidad Juarez Chibuhua Mexico C.P. 32575.The Board o approved Le manufacturer M Banufacturer M USA.16.Legal Proved Le supical suture codes: Dison and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issuedSterile W9510T and W9552Sterile consel les W9510Tstersel and stersel and stersel set supical supical supical supical supical site(s) and codes.	14.	-do-				Approved.
Ms. Unum Zia Shamsi       San Lorenzo, PR USA 00754       Class C       suture for use in abdominal wound closure hernia repair, sternal closure and othopaedic procedures including cerclage and tendon repair.         Ms. Unum Zia Shamsi       San Lorenzo, PR USA 00754       M650G Manufacturing Site: Ethicon, LLC.       M650G Matures M650G Manufactures Shelf Life: 60       sternal closure procedures including cerclage and tendon repair.         15.       -do-       1. Legal Manufacturer: Evaluator: Ms. Unum Zia Shamsi       VicyI™ Manufacturer: Ethicon LLC       Sterile (Polyglactin 910) Suture       Sterile approved Le synthetic absorbable surgical suture frailes Industrial Park, Suture 401 Guaynabo, PR USA. 00969       The Board o approved Le synthetic absorbable surgical suture frailes Industrial Park, Suture 401 Guaynabo, PR USA. 00969       Codes: Gagan Manufacturer: Calle Durango No. Ciduad Juarez       The Board o approved Le synthetic absorbable surgical suture frailes Industrial Park, Suture 401 Guaynabo, PR USA. 00969       The Board o approved Le synthetic advised the firm anufacturer(s) and codes an advised the firm apply separately other le manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and corresponding manufacture(s) and coresponding manufacture(s) and corresponding manufacture(s) and co			,	Steel Suture		
Shamsi00754in abdominal wound closure, htspay 183 Km. 8.3 San Lorenzo, PR USA 00754in abdominal wound closure, htspay 183 Km. 8.3 San Lorenzo, PR USA 00754in abdominal wound closure, htspay 183 Km. 8.3 San Lorenzo, PR USA 0075415do-1. Legal Manufacturer: Ethicon LLC Highway 183 km. 8.3 San Lorenzo, PR USA 00754M400G Monthsothopaedic procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLC Biblion LLC 2015VicryITM Sterile SutureSterile synthetic absorbable synthetic absorbable suici 401 Guaynabo, PR USA. 00969 Manufacturing Site: Ethicon Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.P. 32575.Codes: Legal Manufacturer: Biblion LLC, Guaynabo, PR USA.00969The Board o approved Le manufacturer: advised the firm advised the firm and codes a advised the firm anaufacturing site soft 10 sequence, Ciudad Juarez Ciudad Juarez <br< th=""><th></th><th>Evaluator:</th><th>Highway 183 Km. 8.3</th><th></th><th>stainless steel</th><th></th></br<>		Evaluator:	Highway 183 Km. 8.3		stainless steel	
Imanufacturing Site:       Codes:       wound closure,         Highway 183 Km. 8.3       M650G       sternal closure         San Lorenzo, PR USA       M400G       othopaedic         00754       M400G       othopaedic         (FSC US FDA valid till 08-04-2021)       Shelf Life: 60       including         15.       -do-       1. Legal       VicryI™       Sterile       absorbable         Ms. Unum Zia       Af5 C Street Los       Suture       Synthetic       absorbable       synthetic         Shamsi       Frailes Industrial Park,       Class D       corpolymer       mad ferom       advised the firm         Manufacturing Site:       Ethicon Inc.       Cales:       manufacturer:       and 10% L-       advised the firm         2751 Lote Bravo       Ciada Juarez       USA.       use in general       soft tissue       and coresponding         Ciudad Juarez       L.9.32575.       J442H       approximation       and coresponding       and coresponding         Cibubua Advized       VicryITM       W9391       in ophthalmic       site(s) and codes.         Advised the firm       J434H       soft tissue       and coresponding       and         Chibubua Mexico       J434H       soft tissue       and coresponding </th <th></th> <th>Ms. Unum Zia</th> <th>San Lorenzo, PR USA</th> <th>Class C</th> <th>suture for use</th> <th></th>		Ms. Unum Zia	San Lorenzo, PR USA	Class C	suture for use	
Manufacturing Site: Ethicon, LLC. Highway 183 Km, 8.3 San Lorenzo, PR USA 00754M650G M651Ghernia repair, sternal closure and othopacdic procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLC M5 Unum Zia ShamsiVicryITM (Polyglactin 910) StureSterile synthetic absorbable surgical suture co-polymer made from use in column approved Le absorbable surgical suture co-polymer made from Manufacturers: Ethicon LLC Alter Trailes Industrial Park, Suite 401 Guaynabo, PR USA, 00969Codes: Legal Manufacturer: Legal Manufacturer: Legal Manufacturers D% glycolide and 10% L- Latcide. Logid Juarez Chihuhua Mexico C.P. 32575.The Board or approved Le absorbable surgical suture co-polymer made from use in general J434H W9105 W9221 in cluding use in ophthalmic W9211 including use in ophthalmic w9442 w9391 w9221 including use in ophthalmic w9443 w9510T and vincilaan 15, B E-1831 W9510T w9522hermia repair, stemal closure and corresonsites w9552W9510T W9552mad diameter.		Shamsi	00754		in abdominal	
Manufacturing Site: Ethicon, LLC. Highway 183 Km, 8,3 San Lorenzo, PR USA 00754M650G M651G stemal closure and othopaedic procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLC BiamsiVicryI™ (Polyglactin 910) Suite 401 Guaynabo, PR USA, 0069Sterile synthetic absorbable co-polymer made from glycolide and for solid durateThe Board o approved Le approved Le absorbable co-polymer manufacturing site: Ethicon ILC, Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhu Mexico C.P. 32575.The Board oc approved Le absorbable co-polymer made from and codes a advised the firm apply separately work with and work 443hernia repair, sterile sterile synthetic absorbable co-polymer manufacturing site and codes a advised the firm apply separately work 442H work 410 co-polymer manufacturing site(s) and codes a advised the firm apply separately other le coresponding manufacturing site(s) and codes.15do-1. Legal Manufacturer: Ethicon ILC, Cliudad Juarez Chihuhu Mexico C 2751 Lote Bravo Ciudad Juarez Chihuhu Mexico C 2752.Codes: J434H J434H J434H W9105 W9221 W9221 including use in ophthalmic wysiet(s) and codes.The Board oc approved Le and codes.16.Legal W9391 W9422work surgery, W9510T and W9510T and W9511T W9522hernia repair, and ametr.17.Fce Belgium W9552W9522manufacturer.				Codes:	wound closure,	
Ethicon, LLC.M651Gsternal closureHighway 183 Km, 8,3 San Lorenzo, PR USA 00754MF665and othopaedic procedures including cerclage and tendon repair.15do-I, Legal Manufacturer:Monthscerclage and tendon repair.15do-I, Legal Manufacturer:VicryI™ PC Street Los ShamsiSterile synthetic absorbable suite 401 Guaynabo, PR USA. 00969 Manufacturer:Sterile synthetic absorbable surgical sutureThe Board or approved Le manufacturer M surgical suture15do-I, Legal Manufacturer:VicryI™ Class DSterile synthetic absorbable surgical sutureThe Board or approved Le surgical suture16.Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969 Manufacturing Site: Calle Durango No. 2751 Lote Bravo Citudad Juarez Clidad JuarezClass D Guaynabo, PR USA. 00969 USA. USA. 00969Codes: made from and 10% LC, and 00% glycolide and 10% composed of co-polymer maufacturing si and codes a advised the firm apply separately other le and corresponding manufacturer(s) and corresponding manufacturing si site(s) and codes.16.Legal W9391W99105 in ophthalmic W9443 W9221 including use in cluding use w9520Tmath codes.17.Legal W9510T W9510T W9521T W9521T W9521T W9521TW9511T microsurgery W9521T than 2mmmath codes.			Manufacturing Site:	M650G		
Highway 183 Km. 8.3 San Lorenzo, PR USA 00754MF665 M400Gand othopadic procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLCVicryITM (Polyglactin 910) Suite 401 Guaynabo, PR USA. 00969Sterile synthetic absorbable surgical suture co-polymer manufacturers (Ciudad Juarez Chihuhua Mexico C.751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.752 US FDA valid till 08-04-2021)The Board o approved Le absorbable surgical suture co-polymer made from and 10% L- lactide.The Board o approved Le approved Le absorbable surgical suture co-polymer manufacturing si and codes a advised the firm apply separately other manufacturer(s) and corresponding manufacturing site 401 Guaynabo, PR USA. 00969 PR USA. 00969 PR USA. 00969 PR USA. 00969 Codes: Ciudad Juarez Chihuhua Mexico J434HSterile surgical suture co-polymer and 10% L- lactide. Intended for use in general soft tissue and corresponding manufacturing site(s) and codes.2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issuedW95107 W9522and diameter.W95107 W9552diameter.W9552diameter.			0			
San Lorenzo, PR USA 00754M400G procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLC Manufacturer: BhamsiVicryITM (Polyglactin 910)Sterile synthetic absorbable surgical suture composed of co-polymer made from proved use surgical suture co-polymer made from and codes a and co						
0075400754procedures including cerclage and tendon repair.15do-1. Legal Manufacturer: Ethicon LLC ShamsiNonthssterile synthetic absorbable Surgical sutureThe Board or approved Le absorbable surgical suture15do-1. Legal Manufacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969 PR USA. 00969VicryITM Codes: Legal Manufacturer: Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chiuhua Mexico C.P. 32575.Codes: Legal Manufacturer: USA. USA.The Board or approved Le synthetic absorbable surgical suture co-polymer made from and codes a advised the firm apply separately other le manufacturing site cliudad Juarez Chiuhua Mexico C.P. 32575.The Board or approved Le surgical suture co-polymer manufacturer: lactide. Intended for use in general and coresponding manufacturer(s) and corresponding manufacturer(s) and corresponding manufacturer(s) and corresponding manufacturer(s) and codes.2. Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issuedW9552manufacturer.			e .			
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Isdo-I.LegalMonthscerclage and tendon repair.Isdo-I.LegalVicryITMSterileapprovedMs. Unum ZiaEthicon LLCSuturesynthetic absorbableabsorbableapprovedShamsiFrailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969Codes: Ethicon LLC, Manufacturer: Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chimhuna Mexico C.P. 32575.Codes: Ethicon LLC, Barvier, Calle Durango No. 2751 Lote Bravo Ciudad JuarezIntended for usin general diftion LC, Barvier, Calle Durango No. 2751 Lote BravoIntended for usin general diftion LC, Ciudad JuarezIntended for usin general and 10% L- lactide.manufacturing si and codes a advised the firm apply separately othermanufacturer(s) and advised the firm approximation and coresponding manufacturing site(s) and codes.It los-04-2021)W9221 W9105including use in ophthalmic W9391 in ophthalmic Manufacturer: W9442surgery, w9442 surgery, W9443 in ophthalmic including use including use in			00734	Shalf I if a 60	-	
Image: till 08-04-2021)tendon repair.15do-1. LegalVicryI <sup>M</sup> SterileEvaluator: Ms. Unum Zia ShamsiI. LegalVicryI <sup>M</sup> SterileThe Board or approved Le absorbableShamsi475 C Street LosSuturesynthetic absorbableapproved Le manufacturer MFrailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969Codes: Legalcorrespondi made from 90% glycolide and 10% L- late from apply separately other cliudad JuarezCodes: Legalmatufacturing and other corpoymerCBC.P. 32575. (FSC US FDA valid till 08-04-2021)USA.Use in general otherand codes a and codes a <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>						
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Is.Rs. 50,000/-15do-I. LegalVicryI™SterileWanufacturer:(Polyglactin 910)syntheticabsorbableShamsiFrailes Industrial Park,Sutureabsorbablesurgical sutureShamsiFrailes Industrial Park,Class Dcomposed ofco-polymerPR USA. 00969Codes:made fromadvised the firmManufacturing Site:LegalManufacturer:and 10% L-Ethicon Inc.Ethicon Inc.Ethicon LLC,lactide.Cildad JuarezUSA.USA.use in generalChihuhua MexicoJ434Hsoft tissueandC.P. 32575.J442HapproximationManufacturer:J434Hsoft tissueUSA.W9105ligation,till 08-04-2021)W9105ligation,W9221including useJohnson and JohnsonW9442Vincrilaan 15, B E-1831W9510TDiegem, BelgiumW9552W9552diameter.			till 08-04-2021)		tendon repair.	
15.       -do- Manufacturer: Evaluator: Ms. Unum Zia Shamsi       1. Legal Manufacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969       VicryI™ (Polyglactin 910) Suture       Sterile synthetic absorbable surgical suture composed of co-polymer made from 90% glycolide and 10% L- lactide. Intended for USA.       The Board of approved Le manufacturer M Ethicon LLC a its correspondin manufacturing si ethicon LLC, Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuhua Mexico C.P. 32575.       Sterile Suture       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 corresponding manufacturers; Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium (FSC Belgium issued       VicryI™ (VicryI™ Class D       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 corresponding manufacturers; W9221       The Board of approved Le manufacturing si and codes a advised the firm and corresponding manufacturing site(s) and codes.						
Evaluator: Ms. Unum Zia ShamsiManufacturer: Ethicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969(Polyglactin 910) Suturesynthetic absorbable surgical suture composed of co-polymerapproved Le manufacturer M Ethicon LLC a its correspondi advised the firm apply separately other le manufacturersManufacturing Site: Ethicon Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Ciudad Juarez CPR USA. 00969Codes: Legal Manufacturer: and 10% L- lactide.and codes a advised the firm apply separately other le manufacturer(s) and corresponding manufacturer(s) and corresponding manufacturing site(s) and codes.Vincilan 15, B E-1831 Vincilan 15, B E-1831 Diegem, BelgiumW9552synthetic absorbable surgical sutureapproved Le manufacture M Ethicon LLC a manufacturer: and codes a and codes a and corresponding manufacturing site(s) and codes.						
Evaluator: Ms. Unum Zia ShamsiEthicon LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA. 00969Sutureabsorbable surgical suture composed of co-polymer made from 90% glycolide and 10% L- lactide.manufacturer M Ethicon LLC a its correspondi manufacturing si and codes a advised the firm apply separately other le manufacturer(s) and corresponding manufacturer(s) and codes a advised the firm apply separately other le manufacturer(s) and corresponding manufacturer(s) and 	15.	-do-	0	5		<b>v</b>
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			W9567 W9580T W9581T W9582T W9718 W9719 W9828 Legal Manufacturer: Johnson and Johnson International, Belgium W9023 W9024 W9025 W9106 W9130 W925 W9106 W9130 W9350 W9377 W9378 W9378 W9377 W9378 W9890 W9375 W9500T W9514T W9531T W9566 W9575 W9501T W9531T W9566 W9575 W9831T W9832T FSC of US FDA and Belgium does not have codes. The manufacturer		
			W9514T W9531T W9566 W9575 W9831T W9832T FSC of US FDA and Belgium does		
			Fee submitted: Rs. 50,000/-		
16.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma	Manufacturer: Response Biomedical Corporation, 1781-75 <sup>th</sup> Avenue W.,	Ramp® Procalcitonin Controls Class C	Intended for invitro diagnostic use in the quality	Approved.

17.	Court, Main Clifton Road, Karachi (ELI-00030) <u>Evaluator:</u> Ms. Unum Zia Shamsi	Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017) Manufacturer:	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/- EASYMAX®	control of the accuracy of the RAMP calcitonin assay	Approved subject
17.	Care Impex, 1 <sup>st</sup> Floor Al- Falah Chambers, Tilak Road Hyderabad. (ELI-00357) <b>Evaluator:</b> Ms. Unum Zia Shamsi	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)	Mini Self- Monitoring Blood Glucose System. Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	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- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1102]	Legal Manufacturer: EPS Bio Technology Corp No. 8 R&D Rd III, HsinchuScien Park, Sinchu, T <i>aiwa</i> n 30077 ROC. (FSC T <i>aiwa</i> 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) <u>Evaluator:</u> Ms. Unum Zia Shamsi	Legal Manufacturer: BARD PERIPHERAL VASCULAR, INC. 1625 W 3 <sup>RD</sup> 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	<b>Approved</b> subject to provision of valid Free Sale Certificate duly attested by Embassy of Pakistan.
20.	-do- <b>Evaluator:</b> Shahid Muhammad Iqbal	Legal Manufacturer: Bard Peripheral Vascular, Inc. 1625W 3 <sup>rd</sup> 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 endarterectom y procedure.	<b>Approved</b> subject to provision of updated LOA and Confirmation of shelf life claim.
21.	-do- <b>Evaluator:</b> 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.	<b>Approved</b> subject to provision of updated LOA, ISO for manufacruing site and Shelf-life supported by studies.

		Shelf Life 3 years		
	ECCLICA			
	FSC USA	Rs.50,000/-		
	Valid till, September,			
	05,2020		A	
22.	Legal Manufacturer:	Angiomed PTFE	A guide wire,	Approved subject
		COATED	for	to provision of
	Angiomed GmbH &	<b>GUIDE WIRE</b>	interventional	MRP, Valid ISO
	Co. Medizintechnik		procedures.	and
	KG, Wachausstrasse	02200020		Real time Shelf life
	6, 76227 Karlsruhe,	02200030		studies.
	Germany	02200040		
	72.2.2	02200050		
	FSC Germany	02200080		
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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	03300050 03350030 03350040 03350050 03370050 03390050 03410020 03410020 03410030 03410050 03410055 03410055 03410060 03410070 03410070 03410070 03410080 03430020 03430020 03430030 03430040 03430040 03430050 03430080 03670050 Class D Shelf Life 3 years Angiomed PERCUTANEO US KIDNEY DRAINAGE 55000010 55000030 55000040 55000080 55000090	A catherization method use to drain the kidneys, when an obstruction has blocked the urinary passage.	Approved subject to provision of Valid ISO.
			55000090 Class C Shelf Life 3 years		
			Rs.50,000/-		
24.	-do- <b>Evaluator:</b> Shahid Muhammad Iqbal	Legal Manufacturer: Bard Access System, Inc. 605 North 5600 West Salt Lake City, UT USA.	X- PORT <sup>™</sup> isp Implantable port 0607500, 0607510, 0607520, 0607525,	The X- port isp ™ Implantable ports are indicated for patient therapies requiring	Approved subject to provision of valid Design Examination Certificate and updated LOA
		Manufacturing Sites:	0607530,	repeated access	

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		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, 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- <b>Evaluator:</b> 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.	<b>Approved</b> subject to provision of Executive summary of shelf life
26.	-do- <b>Evaluator:</b> 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 5 <sup>th</sup>	Bard® 3D Max <sup>™</sup> Light Mesh 0117310 0117311 0117320 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- <b>Evaluator:</b> 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) <u>Evaluator:</u> 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.6 5-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 <sup>™</sup> 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- <b>Evaluator:</b> Ms. Unum Zia Shamsi	Manufacturer: M/s. Yangzhou Goldenwell Medical Devices Factory, No. 16 Tengfei Road, Dinggou Industrial	Cure <sup>™</sup> Burette Infusion Set Class B Size: 100ml Shelf Life: 05 years	Sterile, single- use burette infusion set	Approvedsubjecttoforeigninspectionofmanufacturerabroad. The Boardalso 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- <b>Evaluator:</b> 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 <sup>™</sup> 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- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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	Approvedsubjecttoforeigninspectionofmanufacturer

		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) <u>Evaluator:</u> 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) <u>Evaluator</u> : 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 resynchronizat ion 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) <b>Evaluator:</b> 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 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

IZ:t 50 tooto
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
AESKUSLIDES rLKS (wrapped)
Kit 50 tests
Ref: 517.050
Shelf life: 18
months
AESKUSLIDES rLKS (compared)
rLKS (separated) Kit 50 tests
Ref: 517.051
Shelf life: 18
months
11.AESKUSLID
ES 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- <b>Evaluator:</b> 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-	Rs. 25,0007- DIRUI H 100 Urine Analyzer (Urine Analyzer) Class B Analyzer Life: 7 Years Shelf Life: Strips 24 Months	Urine Analyzer	ApprovedsubjecttoforeigninspectionofmanufacturerabroadorproviosionofCEmarkingt

		12-2020)	Sheath 18 Months Detergents 12 Months (Sizes & Codes as Per FSC) Strips codes: ???? Rs.25,000/-		documentsorevidecnceofregistrationofreference.countries.TheBoardalsoauthorizedtheSecretaryMDBtoissueregistrationofthepanelofexpertsapprovethemanufacturingplant.
39.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) [1131] <b>Evaluator:</b> 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- <b>Evaluator:</b> 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.

		Minnoonalia MM	Do 50 000 /	thoropostic	
		Minneapolis, MN	Rs.50,000/-	therapeutic	
		55428 USA	(Sizes & Codes as	interventions	
			Per FSC)	or patients	
		Contract		transportation.	
		Manufacturer:		The device	
		MedplastMedical Inc.		immobilizes a	
		620 Watson Sw GR.		body part by	
		MI USA 49504		encompassing	
				it and then	
		(FSC US FDA valid		apply a	
		till 03-01-2020)		vacuum The	
		tiii 03-01-2020)		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-	Legal Manufacturer:	DLP® Femoral	A sterile or	Approved subject
		Medtronic, Inc. 710	Arterial Cannula	semi-rigid tube	to provision of
	<b>Evaluator:</b>	Medtronic Pkwy	(Cardiopulmonar	designed to be	stability study
	Hafiz	Minneapolis, MN	y bypass cannula,	inserted into a	having claimed
	Muhammad	55432USA	arterial)	femoral artery	shelf life
	Asif Iqbal		Class D	or vein during	
	[1135]	Manufacturer:	Shelf life 3 Years	cardiopulmona	
	r]	Medtronic Perfusion	Codes&Sizes:	ry bypass	
		Systems	DLP® Femoral	procedures. It	
		7611 Northland Dr	Arterial Cannulae	is typically a 9	
		Minneapolis,	57414_DLP®	to 24 Fr tube	
		<b>-</b>	Femoral Arterial	with an end	
		MN55428 USA	Cannulae		
				hole (some	
		Contract	57417_DLP®	may include	
		Manufacturer:	Femoral Arterial	side holes): It	
		MedplastMedical Inc.	Cannulae	is Short	
		620 Watson Sw GR.	57421_DLP®	enough to keep	
		MI USA 49504	Femoral Arterial	the distal tip	
			Cannulae	inside the	
		(FSC US FDA valid	57517_DLP®	femoral vessel.	
		till 08-03-2020)	Art Cannula,	The tube is	
		,	Femoral, 3/8"	used in set	
			remotal, 570	useu III sel	
			Non Vented	ups/ systems	

			Connector, 17 Fr 57521_DLP® Art Cannula, Femoral, 3/8" Non Vented Connector, 21 Fr <b>Rs.50,000/-</b>	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 E1 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-	Legal Manufacturer:	Coagulation	The instrument	Approved subject
	<b>Evaluator:</b> Hafiz	Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN	Instrument –ACT Plus® Automated	is intended for in vitro diagnostic	to provision of Design Examination
	Muhammad	55432 USA	Coagulation timer	testing in either	certificate.

	Asif Iqbal		IVD	a hospital	
	[1139]	Manufacturer:	Class D	laboratory	
	[1139]		Shelf Life : N/A	setting or a	
		Medtronic Perfusion	Codes & Sizes:	point of care	
		Systems 7611 Northland Dr		-	
		7611 Northland Dr	ACT 100- ACT	(decentralized)	
		Minneapolis, MN	Plus®, 100-120V	setting (e.g, in	
		55428 USA	ACT 200- ACT	the operating	
			Plus®, 200-240V	room, cardiac	
		Manufacturing	ACT 20001- ACT	catheterization	
		Facility:	Plus®, 200-240V	lab, intensive	
		M/s Medtronic	ACT 20002- ACT	care unit, or	
		Mexico S.de R.L. de	Plus®, 200-240V	clinic, etc.	
		CV Av. PaseoCucapah	ACT 20003- ACT		
		10510 El Lago	Plus®, 200-240V		
		Tijuana, Baja	ACT 20004- ACT		
		California CP 22210,	Plus®, 200-240V		
		Mexico	ACT 20005- ACT		
			Plus®, 200-240V		
		Manufacturing	ACT 20006- ACT		
		Facility:	Plus®, 200-240V		
		Medtronic Perfusion	ACT 20008- ACT		
		Systems	Plus®, 200-240V		
		18501 E Plaza Dr	ACT 20024- ACT		
		Parker, Co USA	Plus®, 200-240V ACT 20041- ACT		
		80134.			
		(FSC US FDA valid	Plus®, 200-240V ACT 20046- ACT		
		till 13-09-2019)	ACT 20040- ACT Plus®, 200-240V		
	1	expired			
44.	-do-	Legal Manufacturer:	Bio-Medicus®	A Sterile, rigid	Approved.
	<b>T 1</b>	Medtronic, Inc. 710	One Piece	or semi-rigid	
	Evaluator:	Medtronic Pkwy	Femoral	tube designed	
	Hafiz	Minneapolis, MN	Cannulae	to be inserted	Product applied is
	Muhammad	55432 USA	Cardiopulmonary	into a femoral	Bio-Medicus® One
	Asif Iqbal	Manufacturer:	Bypass cannula,	artery or vein	Piece
	[1142]	Medtronic Perfusion	Femoral Class D	during	Femoral(Arterial)C
		Systems	Class D	cardiopulmona	annulae but the
		7611 Northland Dr	Shelf Life: 3	ry bypass	submitted fee is of
		Minneapolis, MN	Years	procedures. It	product Bio-
		55428 USA	Sizes & Codes :	is typically a 9	Medicus <sup>®</sup> One
		N	Bio-Medicus®	to 24 Fr tube	Piece Femoral
		Manufacturer:	One Piece Femoral	with an end	Venous Cannulae.
		Medplast Medical Inc	Cannulae	hole(Some may include	Discus with
1				I HAV HICIUUC	KHALID SAHB
		620 Watson SW GR,		<b>.</b>	
		MI USA 49504	96820-008-Bio-	side holes) it is	
		MI USA 49504	96820-008-Bio- medicus®Art.	side holes) it is a short enough	
		MI USA 49504 (FSC US FDA valid	96820-008-Bio- medicus®Art. Cannula, ¼" non-	side holes) it is a short enough to keep the	
		MI USA 49504	96820-008-Bio- medicus®Art. Cannula, ¼" non- vent con., 8Fr	side holes) it is a short enough to keep the distal tip inside	
		MI USA 49504 (FSC US FDA valid	96820-008-Bio- medicus®Art. Cannula, ¼" non- vent con., 8Fr 96820-010-Bio-	side holes) it is a short enough to keep the distal tip inside the femoral	
		MI USA 49504 (FSC US FDA valid	96820-008-Bio- medicus®Art. Cannula, ¼" non- vent con., 8Fr 96820-010-Bio- medicus®Art.	side holes) it is a short enough to keep the distal tip inside the femoral vessel. The	
		MI USA 49504 (FSC US FDA valid	96820-008-Bio- medicus®Art. Cannula, ¼" non- vent con., 8Fr 96820-010-Bio- medicus®Art. Cannula, ¼" non-	side holes) it is a short enough to keep the distal tip inside the femoral vessel. The tube is used in	
		MI USA 49504 (FSC US FDA valid	96820-008-Bio- medicus®Art. Cannula, ¼" non- vent con., 8Fr 96820-010-Bio- medicus®Art.	side holes) it is a short enough to keep the distal tip inside the femoral vessel. The	

			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, 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 cardiopulmona ry 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.

\u03c8       \u03c8/\u03c8       intended to         \u03c8       \u03c8       \u03c8       \u03c8         \u03c8<		1 / 44		
a       ge830-0012_Bio-Medicus®       patients blood         Medicus®       venous Cannula,       and arterial         Venous Cannula,       pump,       pump,         pump,       pump,       bypassing the         96830-014_Bio-Medicus®       completely.       This is a single         Venous Cannula,       Y" 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.,       12Fr.,         96670-012_Bio-Medicus®       Venous Femoral       Cannula, 3/8"         Venous Femoral       Cannula, 3/8"       non vent con.,         17Fr.,       96670-012_Bio-Medicus®       Venous Femoral         Venous Femoral       Cannula, 3/8"       non vent con.,         21Fr.,       96370-023_Bio-Medicus®       Venous Femoral         Venous Femoral       Cannula, 1/2"       non vent con.,         23Fr.,       96370-023_Bio-Medicus®       Venous Femoral         Venous Femoral       Cannula, 1/2"       non vent con.,				
96830-0112_Bio- Medicus® textmal tubing and attrial %" non-vent con., 12 Fr. 96830-014_Bio- Medicus® Venous Cannula, %" 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., 96670-012_Bio- Medicus® Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-021_Bio- Medicus® Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-021_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, 3/8" non vent con., 21Fr., 96370-025_Bio- Medicus® Venous Femoral Cannula, 1/2" non vent con., 21Fr., 96370-025_Bio- Medicus® Venous Femoral Cannula, 1/2" non vent con., 23Fr., 96370-025_Bio- Medicus®		10 Fr.	divert the	
96830-0112_Bio- Medicus® textmal tubing and attrial %" non-vent con., 12 Fr. 96830-014_Bio- Medicus® Venous Cannula, %" 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. 96670-012_Bio- Medicus® Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-021_Bio- Medicus® Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-021_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, 3/8" non vent con., 21Fr., 96370-025_Bio- Medicus® Venous Femoral Cannula, 1/2" non vent con., 21Fr., 96370-025_Bio- Medicus® Venous Femoral Cannula, 1/2" non vent con., 23Fr., 96370-025_Bio- Medicus®			patients blood	
Medicus®       external tubing and atterial w" non-vent con., 12 Fr.       external tubing and atterial pump, bypassing the heart and lungs completely.         96630-014_Bio- Medicus®       beart and lungs completely.         Venous Cannula, %" non-vent con., 14 Fr.       mon-vent con., 96670-015_Bio- Medicus®         Venous Femoral Cannula, 3/8" non vent con., 15Fr., 96670-017_Bio- Medicus®       use device.         Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96670-012_Bio- Medicus®       non vent con., 19Fr., 96670-012_Bio- Medicus®         Venous Femoral Cannula, 3/8" non vent con., 19Fr., 96370-023_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., 23Fr.,		96830-0012 Bio-		
Venous Cannula, //" non-vent con., 12 Fr. 96830.014_Bio- Medicus® Venous Cannula, //" 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., 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., 23Fr., 96370-025_Bio- Medicus®				
\u03c9       \u03c9       \u03c9       \u03c9         \u03c9       \u03c9       \u03c9       \u03c9       \u03c9         \u03c9       \u03c9       \u03c9       \u03c9       \u03c9       \u03c9         \u03c9 <td< td=""><td></td><td></td><td></td><td></td></td<>				
12 Fr.       bypassing the heart and lungs completely.         Medicus®       completely.         Venous Cannula,       This is a single use device.         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.,       96670-017_Bio- Medicus®         Venous Femoral Cannula, 3/8" non vent con., 17Fr.,       96670-012_Bio- Medicus®         Venous Femoral Cannula, 3/8" non vent con., 19Fr.,       96670-012_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.,       96570-025_Bio- Medicus®		-		
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., 17Fr., 96670-021_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.,				
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Cannula, 1/2" non vent con., 25Fr.,				
non vent con., 25Fr.,				
25Fr.,				
		96370-027_Bio-		
Medicus®				
Venous Femoral		Venous Femoral		

07-11-2019) 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	46.	-do- <b>Evaluator:</b> 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	Cannula, 1/2" non vent con., 27Fr., 96370-029_Bio- Medicus® Venous Femoral Cannula, 1/2" non vent con., 29Fr., Rs.50,000/- 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,	Approved subject to clarification whether the product applied is Cardioblate® 68000 Surgical Ablation System or Cardioblate CryoFlex Surgical Ablation System.
			Ulmerton Road Clearwater, FL USA 33760. (FSC US FDA valid		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 cutting.	

47.	M/s Pharma	M/s. LivaNova USA,	VNS Therapy	included) to transmit the RF electrical current to the operative site: it may additionally be intended to heat an electrode tip. The system,	Approved subject
	Consultant Pakistan (Pvt) Ltd., Suit NO. 207, 207 A Khan Tower, DHA Square Walton Road, Lahore. <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [43-P]	Inc. 100 Cyberonics Boulevard, Houston, TX USA 77058 FSC USFDA Valid till 07.11.2019	Demipulse Model 103Generator (VNS Therapy System) Code/Model: Demipulse generator 103 Class D Shelf Life : 02 years (Generator) Rs.50,000/-	used for vagus nerve stimulation (VNS).	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) <b>Evaluator:</b> 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)	<b>Rejected</b> 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- <b>Evaluator:</b> 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)	<b>Rejected</b> 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- <b>Evaluator:</b> 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)	<b>Rejected</b> 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- <b>Evaluator:</b> 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)	<b>Rejected</b> 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- <b>Evaluator:</b> 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)	<b>Rejected</b> 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.

	(ET 1 00055)		Class D		]
	(ELI-00055)	(i) OMRON Dalian	Class B		
		Co., Ltd(OMD)	Shelf Life: N/A		
	Evaluator:	No.3. Song Jiang	Rs.25,000/-		
	Hafiz	Raod Economic &			
	Muhammad	Technical			
	Asif Iqbal	Development Zone			
	[959]	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			
	1	Valid till 21-03-2024			
55.	-do-	Legal Manufacuturer:	Omron M7 Intelli	The device is a	Approved.
			IT	digital monitor	
	Evaluator:	Omron Healthcare	(Automatic	intended for	
	Ms. Hira	Co., Ltd., 53,	Upper blood	use in	
	Bhutto	Kunotsubo, Terado-	pressure monitor)	measuring	
		cho, Muko Kyoto,		blood pressure	
		617-0002 Japan.	Class B	and pulse rate	
				in adult	
		(FSC Netherland	Shelf Life: N/A	patient.	
		issued 16-05-2019)			
			Sizes & Codes as		
			Per FSC		
			НЕМ-7322Т-Е		
56.	-do-	Legal Manufacuturer:	Omron M3	The device is a	Approved.
		-	(Automatic	digital monitor	
	Evaluator:	Omron Healthcare	Upper Arm Blood	intended for	
	Ms. Hira	Co., Ltd., 53,	Pressure Monitor)	use in	
	Bhutto	Kunotsubo, Terado-		measuring	
		cho, Muko Kyoto,	Class B	blood pressure	
		617-0002 Japan.		and pulse rate	
			Shelf Life: N/A	in adult	
		(FSC Netherland		patient.	
		issued 16-05-2019)	Sizes & Codes as	r	
			Per FSC		
			НЕМ-7131-Е		
57.	-do-	Legal Manufacuturer:	Omron M6	The device is a	Approved.
57.	40		Comfort	digital monitor	· · PP10 / Cu.
	Evaluator:	Omron Healthcare	(Automatic	intended for	
	Ms. Hira	Co., Ltd., 53,	Upper Arm Blood	use in	
				measuring	
	Bhutto	Kunotsubo, Terado-	Pressure Monitor)	measuring	

		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, 9 <sup>th</sup> Floor, NICL Building, AbbasiShaheed Road, Karachi (ELI-00119) <b>Evaluator:</b> 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.	<b>Approved</b> 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- <b>Evaluator:</b> Shahid Muhammad Iqbal	Manufacturer/ Legal Manufacturer: M/s Bausch & Lomb Inc.1400 North Goodman street Rochester, NY USA 14609 Manufacturing Site:	SofLens Soft Contact Lenses, daily wear and extended wear (Polymacon) Class B	Soflens natural colors (daily wear or extended wear 1-7 days)	<b>Approved</b> subject to provisionvalid FQA, Readable labels.

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

			Rs.25,000/-		
64.	-do- <b>Evaluator:</b> 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)	<b>Approved</b> subject to provision of valid FQA, Readable labels.
65.	-do- <b>Evaluator:</b> 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)	<b>Approved</b> subject to provision of valid FQA, Readable labels.
66.	-do- <b>Evaluator:</b> 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 <b>Rs.50,000/-</b>	Multi-Purpose Contact Lens Care Solution	<b>Approved</b> subject to provision of Readable labels.
67.	-do- <b>Evaluator:</b> Shahid	Use of the second sec	Biotrue® Oneday for Presbyopia (Nesofilcon A) Visibility Tinted Contact Lenses	Soft Corrective Contact Lenses, daily Disposable (Nesofilcon A)	<b>Approved</b> subject to provision of valid FQA, Readable labels.

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	Muhammad Iqbal	USA 14609 <b>Manufacturing Site:</b> 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- <b>Evaluator:</b> Shahid Muhammad Iqbal	29-08-2020Legal Manufacturer:M/s Bausch & LombInc.1400 North Goodmanstreet Rochester, NYUSA 14609Manufacturing Site:M/s Bausch & LombIrelandUnit 424/425, ContactLens DivisionIndustrial Estate, CorkRd Waterford,Munster, IrelandFSC USFDAValid Till29-08-2020	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- <b>Evaluator:</b> 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)	<b>Approved</b> subject to provision of valid FQA, Readable labels.

70.	-do- <b>Evaluator:</b> 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	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	<b>Approved</b> subject to provision of valid FQA, Readable labels.
71.	-do- <b>Evaluator:</b> Shahid Muhammad Iqbal	29-08-2020 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).	<b>Approved</b> subject to provision of valid FQA, Readable labels.
72.	-do- <b>Evaluator:</b> 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.	<b>Approved</b> 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) <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1011]	Legal Manufacturer: Sofradim Production, 116 avenue du Formans, France (FSC FRANCE issue date 30-09-2016)	Parietene <sup>TM</sup> Light weight Mesh Abdominal Hernia surgical Mesh, Synthetic Polymer, non-bio absorbable. Class C Shelf Life 5 Years. Codes / Sizes: (TCM1106, TCM1106, TCM1106X3, TCM1510, TCM1510, TCM1515, TCM1515, TCM1515, TCM1515, TCM10200, TCM2020X3, TCM2020X3, TCM3015, TCM3030, TCM4530) Rs.50,000/-	Parietene <sup>™</sup> 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- <b>Evaluator:</b> 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.

		(Hangzhou) Co., Ltd. No. 210 Zhenzhong	Months Rs.50,000/-	Blood Glucose Meter to	
		Road West Lake		measure the	
		District Hangzhou, Zhejiang China.		glucose concentration	
		FSC US FDA Valid		In in whole	
		till (25-12-2020)		blood.	
		FSC US FDA Valid		01000.	
		till (25-12-2020)			
76.	-do-	Legal Manufacturer:	COVIDIEN	Bone Wax is	Approved subjet to
		8	Bone Wax <sup>TM</sup>	indicated for	foreign inspection
	<b>Evaluator:</b>	PolysutureIndustria E	(Heamostatic	use in the	of manufacturer or
	Hafiz	ComercioLtda,	Bone Wax)	control of	provision of CE
	Muhammad	Av. vereador Gabriel	Surgical	bleeding form	marked document.
	Asif Iqbal	ramos da silva, 1245	Heamostatic	bone surfaces.	The Board also
	[1107]	Sao Sebastiao Do	Agents		authorized the
		Paraiso – Mg CEP,	Class C		Secretary MDB to
		37950-000,	Shelf Life: 3		issue registration of
		BRASIL	Years		the product, if the
		Manufacturing Site.	Sizes & Codes:		panel of experts
		PolysutureIndustriaCo	Bar: 50 mm (		approves the
		mercioLtda, Brazil.	Length) x 20 mm		manufacturing
		(FSC Brazil Issuance	(width) x 2.5 mm		plant.
		03-12-2018)	(Thickness), Stick		
			: 25 mm ( Length)		
			x 11 mm		
			(diameter) Rs.50,000/-		
77.	-do-	Legal Manufacturer:	KANGDI	The	Approved subject
		Changzhou Kangdi	Disposable Skin	Disposable	to provision of
	<b>Evaluator:</b>	Medical Stapler Co.,	Stapler	Skin Stapler is	proof of fee for the
	Hafiz	Ltd., No. 16, Kulun	Class B	mainly used	said product.
	Muhammad	Road, Xinbei Zone,	Shelf Life :3	for surgical	1
	Asif Iqbal	213022 Changzhou,	Years	stapling of	
	[1153]	China.	Sizes & Codes:	superficial	
			KYPS-	skin in human	
		(FSC Germany,	25R/KYPS-	body wound	
		Issued on 03-12-2018)	25W/KYPS-	and operative	
			35R/KYPS-35W	incision.	
	1		Rs.25,000/-	/TTL. 1' 11	
78.	-do-	Legal Manufacturer:	Rs.25,000/- KANGDI Sterile	The disposable	Approved.
78.			Rs.25,000/- KANGDI Sterile Disposable	Circular	Approved.
78.	Evaluator:	Changzhou Kangdi	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler	Circular Stapler is	Approved.
78.	<b>Evaluator:</b> Hafiz	Changzhou Kangdi Medical Stapler Co.,	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C	Circular Stapler is mainly used	Approved.
78.	<b>Evaluator:</b> Hafiz Muhammad	Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C Shelf Life: 3	Circular Stapler is mainly used for creation of	Approved.
78.	<b>Evaluator:</b> Hafiz Muhammad Asif Iqbal	Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone,	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C Shelf Life: 3 Years	Circular Stapler is mainly used for creation of end-to-end,	Approved.
78.	<b>Evaluator:</b> Hafiz Muhammad	Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone, 213022 Changzhou,	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C Shelf Life: 3 Years Sizes & Codes:	Circular Stapler is mainly used for creation of end-to-end, end to side and	Approved.
78.	<b>Evaluator:</b> Hafiz Muhammad Asif Iqbal	Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone,	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C Shelf Life: 3 Years Sizes & Codes: KYGW-	Circular Stapler is mainly used for creation of end-to-end,	Approved.
78.	<b>Evaluator:</b> Hafiz Muhammad Asif Iqbal	Changzhou Kangdi Medical Stapler Co., Ltd., No. 16, Kulun Road, Xinbei Zone, 213022 Changzhou,	Rs.25,000/- KANGDI Sterile Disposable Circular Stapler Class C Shelf Life: 3 Years Sizes & Codes:	Circular Stapler is mainly used for creation of end-to-end, end to side and side to side	Approved.

			28.5/ KYGW-31.5/ KYGW-33.5/ KYWC-17.5/ KYWC-21.5/ KYWC-23.5/ KYWC-25.5/ KYWC-31.5/ KYWC-31.5/ KYWCL-21.5 KYWCL-23.5/ KYWCL-25.5/, KYWCL-25.5/, KYWCL-28.5/ KYWCL-23.5/ 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- <b>Evaluator:</b> 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)	KANGDIDispos able 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, KYGZB-33.5, KYGZB-33.5, GCH32, 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- <b>Evaluator:</b> 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	<b>Approved</b> subject to provision of valid Notarized ISO & FQA.

		Germany			
			Rs.25,000/-		
		FSC Germany			
		Issuance			
01		21-11-2018			
81.	M/s. Siemens Healthcare Pvt Ltd., 4th Floor, State Life Building 15-A, Sir Agha Khan Road, Lahore. ELI-00146 <b>Evaluator:</b> 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	<b>BiographmCT</b> BiographmCT S 20 Excel BiographmCT S (20) - 3R BiographmCT S (20) - 4R BiographmCTS (40) - 3R BiographmCTS (40) - 4R BiographmCTS (64) - 3R BiographmCTS (64) - 4R BiographmCT X - 3R BiographmCT X - 4R BiographmCT X - 4R BiographmCT Flow 20 - 4R BiographmCT Flow 20 - 4R BiographmCT Flow 40 - 4R BiographmCT Flow 40 - 4R BiographmCT Flow 40 - 4R BiographmCT Flow 64 - 3R BiographmCT Flow 64 - 3R BiographmCT Flow 64 - 3R BiographmCT Flow 64 - 4R BiographmCT Flow 64 - 4R BiographmCT	PET / CT ScannerofDiag nostic Imaging System	Approved subject to the opinion of Dr. Nadeem Ahmed, Radiologist Agha Khan Hospital, Karachi.
82.	-do-	Manufacturer:	Rs. 50,000/- Biograph	PET / CT	-do-
	<b>T</b> 1 .	M/s. Siemens Medical	Horizon	Scanner for	
	Evaluator:	Solutions USA, Inc.,	(PET / CT)	Diagnostic	
	Hafiz	2501 N. Barrington	Biograph Horizon	Imaging	
	Muhammad	Road, Hoffman	Biograph Horizon	System	
	Asif Iqbal	Estates, Illinois, 60192	- 3R		
	[344-P]	USA.	Biograph Horizon		

		ECLICEDA	4D		
		FSC USFDA	– 4R Class C		
		Valid till May 07, 2021			
			Service Life : 10		
			years		
			Fee submitted:		
0.0			Rs. 50,000/-		
83.	M/s The Searle Company Limited, 1st Floor, NICL Building, AbbasiShaheed Road, Karachi (ELI-00057) <b>Evaluator:</b> 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:GB8417368 816 Rs.25,000/-	Sterile Latex Surgical gloves((Powde r 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

<ul> <li>Hafiz Muhammad Asif Iqbal [373-P]</li> <li>86do-</li> <li>Evaluator: Hafiz Muhammad Asif Iqbal [472-P]</li> </ul>		Mount 22F – flip top cap with7.6mm port	ed to	
<b>Evaluator:</b> Hafiz Muhammad Asif Iqbal		22M/15F 170mm Rs.25,000/-	intersurgicalcat herter mounts via standar conical connections.	
	Manufacturer M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHPRA) Issued on 01-03-2016& 2 <sup>nd</sup> FSC issued on 25- 03-2019 containing variant 2830000 - 3L Reservoir Bag, 22F Neck	INTERSURGIC AL 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, 2820000 - Reservoir Bag, 2L	It is use to form a reservoir of respiratory gases as part of a breathing system.	Approved.

			Shelf Life : 05		
87.	-do- <b>Evaluator:</b> 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 01stMarch, 2016	years INTERSURGIC ALFlextube 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	It is used to deliver and remove respiratory gases from a patient via a system of tubing and connectors.	<b>Deferred</b> for provision of 5 years data of stability study.
88.	-do- <b>Evaluator:</b> 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 25 <sup>th</sup> March, 2019	Rs.25,000/- INTERSURGIC ALSentri 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 <sub>2</sub> 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.	<b>Deferred</b> for provision of stability data.
89.	-do- <b>Evaluator:</b> Hafiz Muhammad	Manufacturer M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire,	INTERSURGIC ALCOMPACT BREATHING SYSTEM	It is use to deliver and remove anaesthetic and respiratory	Approved.

Asif Iqbal	United Kingdom.		gases from a	
[473-P]	C	Product Code –	patient via a	
	FSC U.K (MHPRA)	Name	system of	
	Issued on 01 <sup>st</sup> March,	• 2150000 -	tubing and	
	2016	22mm	connectors.	
		Compact,		
		Extendable		
		breathing		
		system with		
		luer elbow,1.5m		
		<ul> <li>2151000 -</li> </ul>		
		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		
		<ul> <li>2161000 -</li> </ul>		
		15mm		
		compact,paed		
		iatricextendab		
		le breathing		
		system with		
		luer		
		elbow,1.5m		
		• 2164000 - 15mm		
		compact		
		paediatricexte		
		ndablebreathi		
		ng system		
		with luer		
		elbow, ,		

			17 '		,
			1Lreservoir		
			bag and 1.5m		
			limb, 2m		
			Class B		
			Shelf Life : 05		
			years		
			Rs.25,000/-		
90.	-do-	Manufacturer	INTERSURGIC	It is used to	Approved subject
90.	-00-			reduce	
	<b>F</b> 1 /	M/s. Intersurgical	ALFLO-		to provision of
	Evaluator:	Limited, Crane House,	GUARD	microbial	stability data.
	Hafiz	Mollymillars Lane,	BREATHING	transmission in	
	Muhammad	Wokingha, Berkshire,	FILTER	respiratory	
	Asif Iqbal	United Kingdom.	(Breathing Filter)	systems and	
	[469-P]		_ /	reduce	
		FSC U.K (MHPRA)	Class B	bacterial and	
		Issued on 25 <sup>th</sup> March,	Shelf Life : 05	viral	
		2019	years	contamination	
			Codes/Sizes:	of patients,	
			1690000	medical	
			Rs.25,000/-	devices and	
			1\3.23,000/-	equipment.	
91.	-do-	Manufacturer	INTERSURGIC	High	Approved subject
71.	-40-		ALPaediatric	Concentration	
	E	M/s. Intersurgical			to provision of 5
	Evaluator:	Limited, Crane House,	high	Oxygen Mask	years data of
	Hafiz	Mollymillars Lane,	concentration		stablity study.
	Muhammad	Wokingha, Berkshire,	Oxygen Mask		
	Asif Iqbal	United Kingdom.	(High		
	[468-P]		Concentration		
		FSC U.K (MHPRA)	Oxygen Mask)		
		Issued on 1 <sup>st</sup> March,	Class B		
		2016	Shelf Life : 05		
			years		
			Codes:		
			Paediatric high		
			concentration		
			Oxygen Mask		
			1192000		
			Rs.25,000/-		
92.	-do-	Manufacturer	Sentri Adult Nsal	It is used to	Approved.
12.	-40-	M/s. Intersurgical	Cannula	deliver oxygen	Thhrow on the second se
	Evaluator:	Limited, Crane House,		into the	
	Hafiz		(Nasal Cannula)		
		Mollymillars Lane,	Product Code –	patient's nose.	
	Muhammad	Wokingha, Berkshire,	Name		
	Asif Iqbal	United Kingdom.	114401 – Sentri,		
	[470-P]		Adult, Nasal		
		FSC U.K (MHPRA)	Cannula with		
		Issued on 25 <sup>th</sup> March,	Curved Prongs		
		2019	and Tube, 2.1m		
			114402 – Sentri,		
			Adult, Nasal		
			Cannula with		

93.	-do- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [376-P]	<b>Legal Manufacturer</b> M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	Curved Prongs Co2 Monitoring Line, Filter and Tube, 2.1m Class B Shelf Life : 05 years Rs.25,000/- Cirrus 2 Nebuliser, , IntersurgicalEcol ite 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	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	Rs.25, 000/- INTERSURGIC AL 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 <sup>TM</sup> Adult Tracheosomy	It is use to deliver	<b>Approved</b> subject to provision of valid

	<b>T</b> 1 ·		26.1	·	
	Evaluator:		Mask	respiratory	FQA.
	Shahid	M/s. Intersurgical	0 1 10000-0	aerosol and	
	Muhammad	Limited.	Code: 1200050	oxygen to a	
	Iqbal	Address: , Crane		patient	
		House Molly Millars	Class B		
		Lane, Wokingham,			
		Berkshire, United	Shelf Life 05		
		Kingdom	years		
		Manufacturing Site:	Rs.25,000/-		
		UAB Intersurgical			
		Arnioniu 60, Pabrade,			
		LT-18170, Lithuania			
		FSC UK			
		Issuance 25.03.2019			
96.	-do-		Interguide	т	Approved subject
	- 1	Legal Manufacturer:	Tracheal Tube	It is	to provision valid
	Evaluator:		Introducer	used to aid intubation by	FQA and ISO for
	Shahid	M/s. Intersurgical	Bougie	guiding and	manufacturer in
	Muhammad	Limited.		shaping airway	China.
	Iqbal	Address: , Crane	8070006	devices.	
		House Molly Millars	8070010	acvices.	
		Lane, Wokingham,	8070015		
		Berkshire, United			
		Kingdom	CLASS B		
		Manufacturing Site:	Shelf life 5 years		
		Well Lead Medical			
		co., Ltd	Rs.25,000/-		
		No. 47, Guomao			
		Avenue South,			
		Hualong, Panyu,			
		Guangzhou, China			
		FSCIIV			
		FSC UK Issuance 25.03.2019			
		15suance 25.05.2019			
97.	-do-	Legal Manufacturer:	Intersurgical	To provide	Approved subject
71.	-40-	M/s. Intersurgical	Oxygen recovery	spontaneously	to provision of valid
	Evaluator:	Limited.	kit, 40 % oxygen	breathing,	FQA.
	Shahid	Address: , Crane	AIL, TU /0 UAYSCII	intubated	· × ·
	Muhammad	House Molly Millars	1040013	patients with	
	Iqbal	Lane, Wokingham,	1040013	supplementary	
	iquu	Berkshire, United		oxygen during	
		Kingdom	Class B	transport and	
			Class D	in the	
		Manufacturing Site:	Shelf Life 05	Recovery	
		UAB Intersurgical	years	Room.	
		Arnioniu 60, Pabrade,	years		
		LT-18170, Lithuania	Rs.25,000/-		
			10.20,000/-		
		1		1	

		FSC UK			
		Issuance 25.03.2019			
98.	M/s Muslim Trading Agencies, 3 Syed Moj Darya Road, Lahore. (ELI-00359) <b>Evaluator:</b> 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 De 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) <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [367-P]	Legal Manufacturer: DemedtitecDiagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance 13-03- 2019 )	Rs.50,000/- 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 firm has applied three ELISA Kits as a Cluster.

100	-do-	Legal Manufacturer:	Stat Sensor	The system	Deferred for
	Evaluator:	Nova biomedical 200	Xpress Creatinine Meter	used in the quantitative	provision of Embassy attested
	Hafiz	Prospect Street	System	determinatio of	Free Sale
	Muhammad	Waltham. MA 02454.	Stat Sensor	Creatinine	Certificate.
	Asif Iqbal	USA.	Xpress Creatinine	(creat) in	
	[370-P]		Meter System	capillar,	
		(FSC valid15-03-2024)	Class B	venous, and	
			Shelf Life: 24	arterial whole blood.	
			Months Codes L:	bioou.	
			Rs.25,000/-		
101	-do-	Legal Manufacturer:	DEMEDITECA	The	Deferred
101	uo	Demedtitec Diagnostic	ndrostenedione	DEMEDITEC	Deterreu
	<b>Evaluator:</b>	GmbH Lise-Meitner	ELISA	Androstenedio	The firm applied
	Hafiz	StraBe 2 D-24145 Kiel	Dihydrotestoster	ne ELISA is	three IVD kits in
	Muhammad	Germany.	one ELISA	an enzyme	one application as
	Asif Iqbal		Testosterone free	immunoassay	Cluster.
	[367-P]	(FSC Issuance13-03-	Androstenedione	for the	Androstenedione
		2019)	ELISA	quantitative in	ELISA
			Dihydrotestostero	vitro	Dihydrotestosteron e ELISA
			ne ELISA Testosterone free	diganostic measurement	Testosterone free
			Class B	of	resubsterone nee
			Shelf Life: 9	Androsternedi	
			Months	one is serum	
			Codes :	and EDTA	
			DE3265	plasma.	
			Androstenedione		
			ELISA		
			DE2330		
			Dihydrotestostero ne ELISA		
			DE2924		
			Testosterone free		
			Rs.25,000/-		
102	-do-	Manufacturer:	Mycobacterium	Enzyme	Approved.
		Demeditec Diagnostics	Tuberculosis IgG	immunoassay	
	Evaluator:	GmbH, Lise-Meitner-	(ELISA kit)	for the	
	Ms. Unum Zia	StraBe 2, D-24145	Class C	detection and	
	Shamsi	Kiel, Germany.	Shelf Life: 12 Months	quantitative determination	
		(FSC Germany issued	Ref No:	of human IgG	
		on 13-03-2019)	DETUB01	antibodies	
			96 wells	against	
			Fee submitted:	Mycobacteriu	
			Rs. 25,000/-	m tuberculosis	
				in serum and	
				plasma	
103	-do-	Manufacturer:	Mycobacterium	Enzyme	Approved.
		Demeditec Diagnostics	Tuberculosis IgM	immunoassay	
		GmbH, Lise-Meitner-	(ELISA kit)	for the	

	T - 1	Star Do 2 D 24145	<u>C1</u> C	1-4-4	
	<b>Evaluator:</b> Ms. Unum Zia Shamsi	StraBe 2, D-24145 Kiel, Germany. (FSC Germany issued	Class C Shelf Life: 12 Months	detection and quantitative determination	
		on 13-03-2019)	Ref No:	of human IgM	
			DETUB03 96 wells	antibodies	
			Fee submitted:	against Mycobacteriu	
			Rs. 25,000/-	m tuberculosis	
			103. 20,0007	in serum and	
				plasma	
104	M/s	Legal Manufacturer:	ANDOCOR Flex	The device is	Approved as Class-
	Flowtronix		line Venous	used to drain	D medical devices
	Systems,	Andocor NV-	Catheter	venous blood	subject to
	Flat No. 02 Al –Ashraf Plaza,	Kwikaard 104 -2980	(Venous Catheter) Class B	from right atrium and	submission of differential fee of
	range Road,	Zoersel- Belgium.	Shelf Life: 5	caval veins.	Rs. 25,000/-
	Rawalpindi.	(FSC Belgium Issue	Years	cuvui veins.	103. 20,0007 -
	(ELI-00217)	Date28-09-2016)	Codes/Sizes:		
	<b>Evaluator:</b>		Flex Line Venous		
	Hafiz		Catheter, Straight,		
	Muhammad		reinforced with		
	Asif Iqbal		lighthouse tip.		
	[424-P]		01V201L8, 01V221L8,		
			01V241L8,		
			01V261L8,		
			01V281L8,		
			01V301L8,		
			01V321L8,		
			01V341L8, 01V361L8,		
			Rs.25,000/-		
105	-do-	Legal Manufacturer:	ANDOCOR	The device	Approved as Class-
		0	Aortic Root	used for	D medical devices
	<b>Evaluator:</b>	Andocor NV-	Cannulae	antegrade	subject to
	Hafiz	Kwikaard 104 -2980	Class B	delivery of	submission of
	Muhammad	Zoersel- Belgium.	Shelf Life: 5	cadioplegia	differential fee of
	Asif Iqbal [410-P]	(FSC Belgium Issue	Years Codes/Sizes:	solution and for venting of	Rs. 25,000/-
	[410-1]	Date28-09-2016)	Aortic root	the heart	
		Duic20 07-2010 j	cannula with vent	during	
			line	cardiopulmona	
			ARC02	ry bypass	
			ARC05	surgery up to	
			ARC08	six hours or	
			ARC10	less. The cannula may	
			Rs.25,000/-	also be used to	
			1.0.20,0007-	aspirate air	
				from the aorta	
				at the	
				conclusion of	

106	-do- Evaluator:	Legal Manufacturer: Andocor NV- Kwikaard 104 -2980	ANDOCOR Retrograde CardioplegiaCan	the cardiac procedure. The retrograde cardioplegia cannula is	<b>Approved</b> as Class- D medical devices subject to
	Hafiz Muhammad Asif Iqbal [418-P]	Zoersel- Belgium. (FSC Belgium Issue Date28-09-2016)	nulae Class B Shelf Life: 5 Years Codes/Sizes: Retrograde CardioplegiaCan nulae RCC01 Rs.25,000/-	intended to be connected to the cardioplegi line for delivery of cardio pleagia solutions and blood into the patients coronary sinus during cardiopulmona ry bypass procedures.	submission of differential fee of Rs. 25,000/-
107	-do- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal	Legal Manufacturer: Andocor NV- Kwikaard 104 -2980 Zoersel- Belgium.	ANDOCOR Flex line two stage venousCatheter Class B Shelf Life: 5 Years	The device used in venous draingae via the right atrium and inferior vena	<b>Approved</b> as Class- D medical devices subject to submission of differential fee of Rs. 25,000/-
	[422-P]	(FSC Belgium Issue Date28-09-2016)	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/-	vavasimulteno usly during cardiopulmona ry by pass surgery up to six hour or less.	
108	-do- <b>Evaluator:</b> 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.	<b>Approved</b> as Class- D medical devices subject to submission of differential fee of Rs. 25,000/-
				The device is used by a cardiovascular	

109 -do Evaluato Hafiz Muhamn	r: Andocor NV-	ANDOCOR Aortic Catheter	surgeon during cardiovascular intervention. The catheter is	
<b>Evaluato</b> Hafiz Muhamn	r: Andocor NV-		intervention.	
<b>Evaluato</b> Hafiz Muhamn	r: Andocor NV-			
<b>Evaluato</b> Hafiz Muhamn	r: Andocor NV-			Approved as Class-
Hafiz Muhamn			intended for	D medical devices
Hafiz Muhamn		Class B	use in	subject to
Muhamn	Kwikaard 104 -2980	Shelf Life: 5	perfusion of	submission of
		Years	the ascending	differential fee of
Asif Iqba	0	Codes/Sizes:	aorta during	Rs. 25,000/-
[423-P]	(FSC Belgium Issue	Aortic Catheter,	Cardiopulmon	103. 25,0007-
	Date28-09-2016)	with luer	ary bypass.	
	Date20-07-2010)	connector with	ary bypass.	
		vent cap.		
		AC201342V,		
		AC221342V,		
		AC201342VFL,		
		AC241342V,		
		AC241342VFL		
		AC241342VH,		
		AC241342VHS,		
		AC241342VW,		
		AC241342VH,		
		AC261342V,		
		AC301342V.		
		Rs.25,000/-		
110 -do	- Legal Manufacturer:		Thearterial	Approved.
	Andocor NV-	Arterial	cannulae	
Evaluato	r: Kwikaard 104 -2980	Cannulae	use in	
Hafiz	Zoersel- Belgium.	Class B	perfusion of	
Muhamn	х U	Shelf Life: 5	the ascending	
Asif Iqba	Date28-09-2016)	Years	aorta during	
[411-P]		Codes/Sizes:	Cardiopulmon	
		A20162V,	ary bypass.	
		B20162V,		
		B20163V,		
		A22162V,		
		B22163V,		
		A24162V,		
		B24162V,		
		B24163V.		
111 -do	- Legal Manufacturer:	Rs.25,000/- ANDOCOR	The device	Approved.
-00		Vent Catheter	used in venting	Approveu.
Evaluato	r: Andocor NV-	Class B	the left heart	
Hafiz	Kwikaard 104 -2980	Shelf Life: 5	during	
Muhamn		Years	cardiopulmona	
Asif Iqba	0	Codes/Sizes:	ry bypass	
[421-P]	(FSC Belgium Issue	PVC Vent	surgery up to	
	Date28-09-2016)	Catheter, closed	six hours or	
	12a(C20-07-2010)	tip, straight	less.	
		PVSBG170	1000.	
		PVSBG 171		

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	[1167]		port	from the	plant.
			Ref: 01404181 Rs.25,000/-	peripheral vascular system injection port option with one way valve and color coded cap for intermittent and safe administration of drug infusion.	The firm should submit valid FSC.
	M/s Parazelsus Pakistan Private Limited, Office No. 201-204, 2 <sup>nd</sup> Floor, Park Tower Shahrah-e- Firdousi, Block-5, Clifton, Karachi. (ELI-00340) <b>Evaluator:</b> 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) X7560CZNNNN NA Rs.50,000/-	Intraoccular Lens (IOL)	Approved subject to provision of original and attested documents, duly filled Form 7A and Stability data.
115	-do- <b>Evaluator:</b> 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/T7560CZYXX XA Rs.50,000/-	Intraocular Lens (IOL)	<b>Approved</b> subject to provision of duly filled Form 7A and Stability data.
116	-do- <b>Evaluator:</b> 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 ReadyIntraoccula r 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.

117	-do- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1210]	(FSC Italy Issuance date 23-05- 2018) 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)	Intraoccular Lens (IOL) Z7560CZNNNN NA Rs.50,000/- Mini Toric ReadyIntraoccula r Lens (IOL) Class C Shelf Life:4 Years Sizes & Codes: Mini Toric ReadyIntraoccula r Lens (IOL) V7560CZNNNN NA Rs.50,000/-	Intraoccular Lens (IOL)	<b>Approved</b> subject to provision of dually filled Form 7A and Stability data.
118	-do- <b>Evaluator:</b> 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) R2560CZPNNN NA Rs.50,000/-	Intra ocular Lens (IOL)	<b>Approved</b> subject to provision of dually filled Form 7A and Stability data.
	M/s Allmed Solutions, A- 21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi (ELI-00029) <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1169]	Legal Manufacturer: Ameco Medical Industries, Industrial Zone B4-Part 119 East 10 <sup>th</sup> 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.	<b>Approved</b> subject to foreign inspection of manufacturer or provision of CE marked documents.
120	-do- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1168]	Legal Manufacturer: Ameco Medical Industries, Industrial Zone B4-Part 119 East 10 <sup>th</sup> 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	<b>Approved</b> subject to foreign inspection of manufacturer or provision of CE marked documents.

				TT 1' 1 '	
			Sizes & Codes: Short Term	Hemodialysis or apheresis.	
			heamodialysisstep	-	
			tip kit Catheter.		
			285/2017/1 De 25.000/		
121	M/s Noor	Legal Manufacturer:	Rs.25,000/- Hamilton-G5	The Hamilton-	Approved.
121	International	Hamilton Medical	(Intensive Care	G5 Ventilator	Appioveu.
	Noor House,	AG, Via Crusch 8,	Ventilator)	is designed for	
	29-D, Block 6,	7402 Bonaduz,	Class C	intensive care	
	PECHS,	Switzerland.	Life: 8 Years	ventilation of	
	Karachi		Sizes & Codes:	adult and	
	(ELI-00061)	(FSC valid 10-07-2021)	Hamilton-G5	pediatric	
	Evaluator:		159005 Rs.50,000/-	patient, and optionally	
	Hafiz		1(3.50,0007-	infant and	
	Muhammad			neonatal	
	Asif Iqbal			patient.s The	
	[1162]			device is	
				intended for	
				use in the	
				hospital institutional	
				environment	
				where health	
				Care	
				professionals	
				provide patient	
				care. Intended use Hamilton-	
				G5/S1Ventilat	
				or is intended	
				for use by	
				properly	
				trained	
				personnel under the	
				direct	
				supervision of	
				a licensed	
				physician.	
122	-do-	Legal Manufacturer:	Hamilton-T1	The Hamilton-	Approved.
	Evolute	Hamilton Medical	(Intensive Care Ventilator)	T1 ventilator is intended to	
	<b>Evaluator:</b> Hafiz	AG, Via Crusch 8, 7402 Bonaduz,	Class C	provide	
	Muhammad	Switzerland.	Life: 8 Years	positive	
	Asif Iqbal	_ /	Sizes & Codes:	pressure	
	[1163]	(FSCSwitzerlandvalid	Hamilton-T1	ventilator	
		till 10-07-2021)	161006,	support to	
			161009	adults and	
				pediatrics, and optionally	
				optionally	

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	TOP-5520 (Syringe Pump) Class C Life: 6 years Sizes & Codes: N/A Rs.50,000/-	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. 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- <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1161]	date 21-11-2018) 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	<b>Approved</b> subject to provision of valid Full Quality Assurance System Certificate.

				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- <b>Evaluator:</b> 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.

126	M/s Novo Nordisk Pharma (Pvt) Ltd, 113, Shahrah e Iran, Clifton, Karachi. (ELI-00264 & 30) <b>Evaluator:</b> 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 31G NovoFine 32G	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/-	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. 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.
		For Following sizes: (NovoFine 30G NovoFine 31G			

127	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e- Jami, Block No.9, Clifton, Karachi (ELI-00006) <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [1125]	Industries LTD. Tatebayashi Plant 2- 19-64, Matsubara, Tatebayashi-shi, Gunma, 274-8518 JAPAN. (FSC Denmark Issuance Date 28-06- 2020) 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.	<b>Approved</b> subject to provision of realtime Stability data for 5 years shelf life.
128	-do- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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/CA39/04/04 4/005A 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.	<b>Deferred</b> for provision of preliminary test data and clinical study data.
130	-do-	Legal Manufacturer:	Stimuplex HNS Compact	Stimuplex @ Compact is	<b>Deferred</b> 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	preliminary test data and clinical study data.
131	M/s Kaumedex, E- 14/2, New Super Town, Link-2, Defence Road, Lahore. (ELI-00162) <b>Evaluator:</b> 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

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	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) <b>Evaluator:</b> 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 <sup>™</sup> Tn-I Test for Cardiac Troponin-I Class C Shelf Life: 20 Months for Kit 12 Months for Control Codes As per FSC ichroma <sup>™</sup> Tn-I Product License No. 17-469 Classification: IVD reagents for cardiac maker.	ichroma <sup>™</sup> 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.
	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 <b>Evaluator:</b> 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.	<b>Approved</b> subject to valid Embassy attested Free Sale Certificate.
134	-do-	<b>Legal Manufacturer:</b> CryoLife Inc., 1655 roberts Blvd. NW,	On-X Ascending Aortic Prosthesis	Aortic bi- leaflet heart valve	Approved.

	<b>Evaluator:</b> 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/biol ogic polymer aorta graft.	
135	-do- <b>Evaluator:</b> 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 (OXYGENATO RS) Class B Shelf Life : 03 years Code: EU5007 Rs.25,000/-	The device specifically designed to perform the various cardiopulmona ry bypass techniques.	Approved subject to provision of Agency Agreement, ISO 13485, Production QA certificate and Stability data & label.
136	-do- <b>Evaluator:</b> 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 (OXYGENATO RS) Class B Shelf Life : 03 years Code: (AG5032) Rs.25,000/-	The device specifically designed to perform the various cardiopulmona ry bypass techniques.	Approved subject to provision of Agency Agreement, ISO 13485, Production QA certificate and Stability data & label.
137	M/s. NwillHeathcar e, Office No. B-9,	<b>Legal Manufacturer:</b> 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) <b>Evaluator:</b> Hafiz Muhammad Asif Iqbal [455-P]	Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. <b>Manufacturing Site:</b> 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 ClassicCondom (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	Approved.
139	-do- <b>Evaluator:</b> 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	<b>One Touch</b> Extra Safe <b>Condom</b> (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Natural Rubber Latex Male Condom (Contraceptive Device)	Approved.
141	-do- <b>Evaluator:</b> 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-	Legal Manufacturer:	One Touch Enjoy	Natural	Approved.
	Evaluator: Hafiz Muhammad Asif Iqbal [455-P]	M/s. Thai Nippon Rubber Industry Public Company Limited, 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120, Thailand. <b>Manufacturing Site:</b> 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	MaxxCondom (Natural Rubber Latex Male Condom) Class C Shelf Life: 5 years Rs.50,000/-	Rubber Latex Male Condom (Contraceptive Device)	
144	M/s	Legal Manufacturer:	1. Versant®	Siemens	Approved subject
	HooraPharma (Pvt) Ltd., WH-01-20-A7- A8, Korangi Creek Industrial Park,	Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. Manufacturing Site:	HCV Genotype 2.0 Assay (LipA) (SMN 10325052 REF	Versant HCV Genotype 2.0 Assay (LipA) is a line probe assay, for in vitro	to provision of updated LOA.

	Karachi (ELI-00037) <b>Evaluator:</b> Shahid Muhammad Iqbal	Fujirebio N.V., Technologiepark 6, 9052 Gent Belgium (FSC UK valid till 31-12-2020)	3. Ha As Cla	06719382) Shelf life : 18 months Versant® HCV Amplification 2.0 Kit (LipA) (SMN 10325050 REF 06718688) Shelf life : 20 months Versant® HCV Control 2.0 Kit (LipA) (SMN 10325051 REF 06719269) Shelf life : 24 months patitis C Virus say ass D .50,000/-	diagnostic use, which identifies HCV. Siemens Versant HCVAmplifica tion 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. Siemen s Versant HCV Control 2.0 Kit (LipA) is	
145	-do-	Legal Manufacturer:		emens Advia	and the versant HCV Genotype 2.0 assay (LiPA) products. The Assay is	Approved.
	<b>Evaluator:</b> Shahid Muhammad Iqbal	M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA <b>Manufacturing Site:</b> M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street Easz Walpole, MA, 02032, USA (FSC UK, Valid Till	ass AI Syj (SI AI Syj Co (SI Cla Sho 12	ntaur SYPH ay DVIA Centaur philis MN 10492493) DVIA Centaur philis Quality ontrol Material MN 10492616) ass C elf Life: Months .50,000/-	an in vitro diagnostic immunoassay for the qualitative determination of antibodies to Treponema Pallidum in human serum or plasma.	

		31-12-2020)			
146	-do- <b>Evaluator:</b> 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) <b>Evaluator:</b> 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.

	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) <u>Evaluator</u> : 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- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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.

152	-do- <b>Evaluator:</b> Shahid Muhammad Iqbal	Kigsohi Gosen,-Shi, Niigata Japan. 959- 1695 FSC USA Validity 15-05-2020 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	Class C Shelf Life: 18 Months Rs.50,000/- ARCHITECT PIVKA-II ARCHITECT PIVKA-II Reagent Kit 2P48-25 ARCHITECT PIVKA-II Reagent Kit 2P48-35 ARCHITECT PIVKA-II Reagent Kit 2P48-35 ARCHITECT PIVKA-II Calibrators 2P48-01 ARCHITECT PIVKA-II Calibrators 2P48-01 ARCHITECT PIVKA-II Controls 2P48-10 Class C Shelf Life: Reagents: 17 months Calibrator and Controls: 23	Quantitative determination of PIVKA-II in human serum or plasma.	Approved.
153	-do- <b>Evaluator:</b> 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	months Rs.50,000/- 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 photocoagulati on of both anterior and posterior segments of the eye including retinal and pan-retinal photocoagulati on 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 <b>PacScan +</b> <b>Model 300A +</b> Class B Shelf Life: N/A Rs.25,000/-	PacScan <sup>™</sup> 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- <b>Evaluator:</b> 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/-	Multifunctiona l 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- <b>Evaluator:</b> 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 <b>PacScan +</b> <b>Model 300AP +</b> Class B Shelf Life: N/A Rs.25,000/-	PacScan <sup>™</sup> Plus is the latest generation ophthalmic biometry instrument.	Approved.
158	-do- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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- <b>Evaluator:</b> 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.

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	Ground Floor, Weal House, 8 Faiz Road, Lahore. ELI-00040 Evaluator: Shahid Muhammad Iqbal	No. 18 I 34522 Esenyurt Istanbul, Turkey. FSC Turkey Validity 4 <sup>th</sup> May, 2020	8699207331295 8699207331301 8699207331318 0.5ML 3P Insuline sterile syringe 8699207351309 8699207351316 8699207351293 1ML Insuline sterile syringe 8699207311266 8699207311297 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- <b>Evaluator:</b> 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 4 <sup>th</sup> 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	11 <sup>th</sup> January, 2019			
	Muhammad Iqbal				
164	-do-	Legal Manufacturer:	Agilia SP TIVA WII IN	Infusion IV Pump	Approved.
	<b>Evaluator:</b> Shahid Muhammad Iqbal	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	Z018997 Class C Service Life: 10 years Rs.50,000/-		
165	-do-	11 <sup>th</sup> January, 2019	Agilia SP MC	Infusion IV	Approved.
	<b>Evaluator:</b> 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 11 <sup>th</sup> January, 2019	IN Z018697 Class C Service Life: 10 years Rs.50,000/-	Pump	
166	-do- <b>Evaluator:</b> 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 11 <sup>th</sup> January, 2019	Agilia SP MC WIFI IN Reference :Z018797 Class C Service Life: 10 years Rs.50,000/-	Infusion IV Pump	Approved.
167	-do- <b>Evaluator:</b> Shahid Muhammad	<b>Legal Manufacturer:</b> M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany	AgiliaVPMCWIFI INZ019797Class CServiceLife:10	Infusion IV Pump	Approved.

	Iqbal	Manufacturing Site: Fresenius Vial S.A.S Le Grand Chemin 38590 Brezinis France. FSC France Issuance 11 <sup>th</sup> January, 2019	years Rs.50,000/-		
168	-do- <b>Evaluator:</b> 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 11 <sup>th</sup> January, 2019	Agilia VP MC WIFI IN Reference :Z019797 Class C Service Life: 10 years Rs.50,000/-	Infusion IV Pump	Approved.
169	-do- <b>Evaluator:</b> 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 11 <sup>th</sup> 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 <u>Evaluator</u> : 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 65/21/32 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.

171	-do-	Manufacturer : M/s. Dr. Arabin	(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/- Arabin® Cerclage Pessary Type	Silicone pessary used to	Approved subject to provision of
	Evaluator: Ms. Unum Zia Shamsi	GmbH & Co., KG, Alfred Herrhousen Str. 44 58455, Witten, Germany. FSC Germany issued on 14.02.2018	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 65/21/35 65/21/32 65/17/32 (sizes not on FSC. Manufacturer has provided dimenison certificate for the above products manufactured by them)	support the cervix in pregnant patients with threatening preterm labor (Funneling / short cervical length). The perforation allows drainage of discharge.	EPSP.
			Shelf Life: 10 years Fee submiited: Rs. 50,000/-		
172	M/s. Elite Traders, House No. B- 342,B-Block, Satellite Town, Rawalpindi. (ELI-00193) <b>Evaluator:</b> 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.

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42004205	5L		
42004206	6L		
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42004214	4R		
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42004308	211		
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42004303	3L		
42004304	4L		
42004305	5L		
42004306	6L		
42004312	2R		
42004318	210		
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42006602 2L
42006603 3L
42006604 4L
42006605 5L
42006606 6L
42006608
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42010216 6
42010219 3,5
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42010204 4
42010205 5
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42010209 3,5
ACS® MB tibial
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42010909 3,5
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42014104 4
42014105 5
42014106 6
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42014002 2
42014003 3
42014004 4
42014005 5
42014006 6
ACS® FB tibial
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	42075106	
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	42075109	
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	ACS® extension	
	stem	
	42014025	
	14/25mm	
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	42014075	
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	ACS® extension	
	stem male taper	
	42014225	
	14/25mm	
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	ACS® LD	
	extension stem	
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	12.5mm	

173	Enterprises FL-11/1/1, Block-6, Gulshan-e- Iqbal, Karachi. (ELI-00285) <b>Evaluator:</b> 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)	metaphyseal component femoral for ACS ®SC 42075122 2 42075123 3 42075124 4 42075125 5 Shelf Life: 05 years Fee submitted: Rs. 50,000/- 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 Pharmaceutica Is (Pvt) Ltd., 500, 5 <sup>th</sup> Floor, Plaza No. 54, Block B, Civic Centre, Phase- IV, Bahria Town, Rawalpindi / Islamabad. ELI-00330 <b>Evaluator:</b> 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-MP182cm x 2cm BS-091"x 1" (2.5cm x 2.5cm) BS-102"x 2" (5cm x 5cm) BS-112"x 4" (5cm x 10cm) BS-124"x 4" (10cm x 10cm) BS-134"x 8" (10cm x 20cm) BS-0TC-281"x 1" (2.5cm x 2.5cm) 2" 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.

175     -do-     Legal Manufacturer: M/s. LifeScience Plus Inc., 2520-A     Blood Stop ® iX (Absorbent M/s. LifeScience Plus Inc., 2520-A     Sterile, internal washotly absorbable for hospital use)     Approved.       175     -do-     Legal Manufacturer: M/s. LifeScience Plus Inc., 2520-A     Blood Stop ® iX (Absorbent absorbable for hospital use)     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.     Legal Manufacturer: M/s. Beijing Takesiman Technology Development Company, Ltd., 5 Li qia duan, Li Tian Rd, Li Qiao, Beijing, China 101304     Sterile, internal during and 0.5"x2" (1.3cm x 5cm)     Approved.       176     M/s.     Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Corporation 300, Boston Scientific Percozsons     Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Corporation 300, Boston Scientific Corporation 300, Boston Scientific Strature Markon Mathboroub, MA     Intended to be used in conjunction with the RF3000     Approved.						
Evaluator: Ms. Unum Zia Shamsi       M's. LifeScience Plus Inc., 2520-A Wyandotte St., Mountain View, CA, 94043, USA.       (Absorbent hemostat for baspital use)       use wholly absorbable for bleeding during and after surgery         Contract       2"x2" (Scm x       for the general population and for those on anticoagulant medications.         M/s. Beijing Takesiman       0.5"x2" (1.3cm x       for those on anticoagulant medications.         Development Company, Ltd., 5 Li qiao duan, Li Tian Rd, Li Qiao, Beijing, China 101304       0.5"x2" (1.3cm x         FSC USFDA Valid till 17.09.2020       B5-iX17 2"x4" (Scm x       2"x4" (Scm x         B5-iX20 2"x14" (Scm x       B5-iX17 2"x4" (Scm x       4"x8" (10cm x         B5-iX20 2"x14" (Scm x       5cm) B5-iX20 2"x14" (Scm x       B5-iX17 2"x14" (Scm x         10k-ix24				years Fee submitted: Rs. 50,000/-		
FerozsonsM/s. Boston ScientificSuperSlim™usedinLaboratoriesLiCorporation 300,Needle Electrodeconjunctionmited, P.OBoston Scientific Way,SystemwiththeFerozsons.Matlborough, MA.Class CRF3000RF3000	175	<b>Evaluator:</b> Ms. Unum Zia	M/s. LifeScience Plus Inc., 2520-A Wyandotte St., Mountain View, CA, 94043, USA. <b>Contract</b> <b>Manufacturer:</b> M/s. Beijing Takesiman Technology Development Company, Ltd., 5 Li qiao duan, Li Tian Rd, Li Qiao, Beijing, China 101304 FSC USFDA	(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:	use wholly absorbable for the control of bleeding during and after surgery for the general population and for those on anticoagulant	Approved.
Amangarh, Nowshera (KPK).01752 USA.Codes: Codes:Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectableEvaluator: Ms. Unum Zia Shamsi01752 USA.Codes: Manufacturing Site: M/s. Boston Scientific Corporation, 780 Brookside Drive Spenser, USA 47460M001262260 LeVeen SuperSlim Needle LeVeen M001262270Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.	176	Ferozsons LaboratoriesLi mited, P.O Ferozsons, Amangarh, Nowshera (KPK). (ELI-00120) <b>Evaluator:</b> Ms. Unum Zia	M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. <b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, 780 Brookside Drive Spenser, USA 47460 FSC US FDA valid till	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	used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable	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- <b>Evaluator:</b> 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, chemotherape utic drug infusion and renal opacification procedures.	Approved.
178	-do- <b>Evaluator:</b> 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) M004EPTR9620 K20 (Large Curve) M004EPTR9620 N40 (Asymmertic Curve) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	Is indicated for use in patient who require catheter-based cardiac electrophysiolo gical mapping (stimulating and recording) and when used in conjuction with a radiofrequency generator, for cardic ablation.	Approved.
179	-do- Evaluator:	<b>Legal Manufacturer:</b> 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/S uper Large Curve) 7F(2.33mm)/2-5- 2mm UPN: M00420SL2820 GTIN:087147297 80519 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2mm UPN: M00420SL2220 GTIN:	Designed for use in intracardiac pacing and recording	Approved.

08714729780489           Bidirectional           Stecrable           Diagnostic           Catheter           (Duodccapolar/S           uper Large Curve)           TF(2.33mm)/2-2-           2mm           UPN:           M00420SL5550           GTIN:           0871472978046           Bidirectional           Stecrable           Diagnostic           Catheter           (Duodccapolar/S           uper Large Curve)           7F(2.33mm)/5-5-           5mm           UPN:           M00420SL21020           GTIN:           08714729780526           Bidirectional           Stecrable           Diagnostic           Catheter           (Duodccapolar/S)           uper Large Curve)           7F(2.33mm)/2-           10-2mm           UPN:           M00420SL28600           GTIN:           08714729780533           Bidirectional           Stecrable           Diagnostic           Catheter           (Duodccapolar/S)           uper Large Curve) <th><u> </u></th> <th></th> <th></th> <th></th>	<u> </u>			
Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2-2- 2mm UPN: M00420SL5550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 2.32-8-2-8-2-8- 2.82-8-2-8-2-8- 2.82-8-2-8-2-8- 2.82-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2				
Diagnostic Catheter (Dudccapolar/S uper Large Curve) 77(2.33mm)/2-2- 2mm UPN: M00420SL5550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 77(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter Quudecapolar/S UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter Quudecapolar/S UPN:M00420SL 220250 GTIN:			Bidirectional	
Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2.2- 2mm UPN: M00420SL550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/5.5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN:			Steerable	
Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2.2- 2mm UPN: M00420SL550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/5.5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) TF(2.33mm)/2- 10.2mm UPN: M00420SL28600 GTIN:			Diagnostic	
(Duodccapolar/S uper Large Curve) 7F(2.33mm)/2-2- 2mm UPN: M00420SL5550 GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: S2-82-82-82-8- 2mm				
uper Large Curve)         7Ff(2.33mm)/2-2-         2mm         UPN:         M00420SL5550         GTIN:         08714729780496         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S         uper Large Curve)         7Ff(2.33mm)/5-5-         5mm         UPN:         M00420SL21020         GTIN:         08714729780526         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S         uper Large Curve)         7F(2.33mm)/2-         10-2mm         UPN:         M00420SL28600         GTIN:         08714729780533         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S         uper Large Curve)         7F(2.33mm)/2-8-         2-82-82-82-02-         8-2-82-82-02-         8-2-82-82-02-         8-2-82-82-82-         202050         GTIN:				
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$				
2mmUPN:M00420SL5550GTIN:08714729780496BidirectionalSteerableDiagnosticCatheter(Duodccapolar/Super Large Curve)7F(2.33mm)/5-5-5mmUPN:M00420SL21020GTIN:08714729780526BidirectionalSteerableDiagnosticCatheter(Duodccapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:08714729780533BidirectionalSteerableDiagnosticCatheter(Duodccapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:Catheter(Duodccapolar/Super Large Curve)7F(2.33mm)/2-8-2-8-2-8-2-8-2-8-2-8-2-8-2mmUPN:M00420SL220250GTIN:				
UPN: M00420SL5550 GTIN: 08714729780496 Bidirectional Stecerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8-2-8-2- 2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8				
M00420SL5550 GTTN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTTN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTTN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTTN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8-2- 2-8-2-8-2-8-2-8-				
GTIN: 08714729780496 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F7(2.33mm)/5-5- 5mm UPN: M000420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8-2-8-2- 2-8-2-8-2-8-2-8-2-8-2- 2mm UPN:M00420SL 220250 GTIN:			UPN:	
08714729780496BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/5-5-5mmUPN:M00420SL21020GTIN:08714729780526BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:08714729780533BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:08714729780533BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8			M00420SL5550	
08714729780496BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/5-5-5mmUPN:M00420SL21020GTIN:08714729780526BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:08714729780533BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-10-2mmUPN:M00420SL28600GTIN:08714729780533BidirectionalSteerableDiagnosticCatheter(Duodecapolar/Super Large Curve)7F(2.33mm)/2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8			GTIN:	
Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 8-2-8-2-8-2-8- 2-8-2-8-				
Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M000420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M000420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M000420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 8-2-8-2-8-2-8-2- 8-2-8-2-				
Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8 2-82-82-82-8- 2mm UPN:M00420SL 220250 GTIN:				
Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/5.5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2.8-2.8-2.60-2. 8-2-8-2-8-2. 2mm UPN:M00420SL 220250 GTIN:				
(Duodecapolar/S uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
uper Large Curve) 7F(2.33mm)/5-5- 5mm UPN: M00420SL21020 GTTN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTTN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8- 2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8				
$\begin{array}{c} \overline{TF}(2.33 mm)/5.5-\\ 5mm\\ UPN:\\ M00420SL21020\\ GTIN:\\ 08714729780526\\ Bidirectional\\ Steerable\\ Diagnostic\\ Catheter\\ (Duodecapolar/S\\ uper Large Curve)\\ 7F(2.33mm)/2-\\ 10.2mm\\ UPN:\\ M00420SL28000\\ GTIN:\\ 08714729780533\\ Bidirectional\\ Steerable\\ Diagnostic\\ Catheter\\ (Duodecapolar/S\\ uper Large Curve)\\ 7F(2.33mm)/2-\\ 10.2mm\\ UPN:\\ M00420SL28000\\ GTIN:\\ 08714729780533\\ Bidirectional\\ Steerable\\ Diagnostic\\ Catheter\\ (Duodecapolar/S\\ uper Large Curve)\\ 7F(2.33mm)/2-8-\\ 2-8-2-8-2-8-2-8-\\ 2-8-2-8-2-8-2-8-\\ 2mm\\ UPN:M00420SL\\ 2200250\\ GTIN:\\ \end{array}$				
Smm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-82-8-2-8-2-8- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
Smm UPN: M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-82-8-2-8-2-8- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:			7F(2.33mm)/5-5-	
UPN: M00420SL21020 GTIN: 08711729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
M00420SL21020 GTIN: 08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8 2-8-2-8-2-8-2-60-2- 8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-				
GTIN:       08714729780526         Bidirectional       Steerable         Diagnostic       Catheter         (Duodecapolar/S       uper Large Curve)         7F(2.33mm)/2-       10-2mm         UPN:       M00420SL28600         GTIN:       08714729780533         Bidirectional       Steerable         Diagnostic       Catheter         (Duodecapolar/S       uper Large Curve)         7F(2.33mm)/2.8       2.8-2.8-2.60-2.         8-2-8-2-8-2-8-2.       2.8-2-8-2-8-2.         20250       GTIN:         0       GTIN:				
08714729780526 Bidirectional Steerable Diagnostic Catheter (Duodcapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-8-2-				
Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M000420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8- 2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
(Duodecapolar/S uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
uper Large Curve) 7F(2.33mm)/2- 10-2mm UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-60-2- 8-2-8-2-8-2-8-2- 2mm UPN:M00420SL 220250 GTIN:				
7F(2.33mm)/2-         10-2mm         UPN:         M00420SL28600         GTIN:         08714729780533         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S)         uper 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:M00420SL         220250         GTIN:				
7F(2.33mm)/2-         10-2mm         UPN:         M00420SL28600         GTIN:         08714729780533         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S)         uper 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:M00420SL         220250         GTIN:			uper Large Curve)	
10-2mm         UPN:         M00420SL28600         GTIN:         08714729780533         Bidirectional         Steerable         Diagnostic         Catheter         (Duodecapolar/S)         uper 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:M00420SL         220250         GTIN:				
UPN: M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
M00420SL28600 GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
GTIN: 08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
08714729780533 Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
Bidirectional Steerable Diagnostic Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
Steerable Diagnostic Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
Diagnostic Catheter (Duodecapolar/S uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
Catheter (Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
(Duodecapolar/S uper 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:M00420SL 220250 GTIN:				
uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
uper Large Curve) 7F(2.33mm)/2-8- 2-8-2-8-2-80-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:			(Duodecapolar/S	
7F(2.33mm)/2-8- 2-8-2-8-2-8-2-60-2- 8-2-8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
2-8-2-8-2-60-2- 8-2-8-2-8- 2mm UPN:M00420SL 220250 GTIN:				
8-2-8-2-8-2 2mm UPN:M00420SL 220250 GTIN:				
2mm UPN:M00420SL 220250 GTIN:				
UPN:M00420SL 220250 GTIN:				
220250 GTIN:				
GTIN:				
08/14/29/80540				
Bidirectional			Bidirectional	

r - r			
		Steerable	
		Diagnostic	
		Catheter	
		(Duodecapolar/S	
		uper Large Curve)	
		7F(2.33mm)/2-	
		20-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-	
		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-	
		5mm	
		UPN:	
		M00420M270280	
		GTIN:	
		08714729780588	
		Bidirectional	 
	•	·	•

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

			Shelf Life: 3		
			Years		
			Fee submitted:		
			Rs. 50,000/-		
181	-do-	Legal Manufacturer:	Placehit <sup>™</sup> Biliary	To be used to	Approved.
101	-40-	Boston Scientific	Wallstent <sup>TM</sup>	help maintain	Appioved.
	Evaluator:	Corporation	(Endoprosthesis	bile duct	
	Ms. Unum Zia	300, Boston Scientific	for transhepatic	patency in the	
	Shamsi	Way, Marlborough,	use)	following	
	onumbr	MA 01752 USA.	Class C	patient	
		Manufacturing Site:	Codes:	candidates:	
		Boston Scientific	H965SCH650700	a) Patients	
		Limited	Wallstent PT 07F	presenting	
		Business and	08 050	pancreatic	
		Technology Park,	H965SCH650710	carcinoma	
		Model Farm Road,	Wallstent PT 07F	which is	
		Cork, Ireland.	08 070	compressing	
		FSC Ireland valid till	H965SCH650730	the biliary tree.	
		12-04-2023	Wallstent PT 07F	b) Patients	
			10 050	presenting	
			H965SCH650740	cholangiocarci	
			Wallstent PT 07F	noma which	
			10 070	has led to	
			H965SCH650750	biliary	
			Wallstent PT 07F	obstruction.	
			10 090 Shalf Life 24	c) Patients	
			Shelf Life: 24	presenting an	
			Months Fee submitted:	extra-hepatic	
			Rs. 50,000/-	biliary obstruction	
			KS. 50,0007-	due to	
				gallbladder	
				carcinoma,	
				metastases, or	
				ampullary	
				carcinoma.	
				Any use other	
				than that	
				indicated is not	
				recomended.	
182	-do-	Legal Manufacturer:	IntellaTip MiFi	Therapeutic,	Approved.
		Boston Scientific	XP Temperature	temperature-	
	Evaluator:	Corporation	Ablation	controlled,	
	Ms. Unum Zia	300, Boston Scientific	Catheter	cardiac	
	Shamsi	Way, Marlborough,	Class D	ablation	
		MA 01752 USA.	Codes:	catheters	
		Manufacturing Cita	M004EPM45000	designed for use in	
		Manufacturing Site: Boston Scientific	(Standard Curve)	intracardiac	
			8mm x 8F M004EPM4500K	ablation,	
		Corporation, 302 Parkway, Global	20	mapping and	
		Park, Heredia, Costa	(Large Curve)	pacing	
		Faik, Heleula, Costa	(Laige Cuive)	pacing	

		Rica	8mm x 8F		
		Nica	8mm x 8F M004EPM4500N		
		FSC Ireland valid till	40		
		10-11-2020	(Asymmetric		
		10 11 2020	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-	Legal Manufacturer:	AngioJet <sup>TM</sup>	Intended for	Approvedsubject to
100	40	Boston Scientific	ZelanteDVT <sup>TM</sup>	use with the	provision of valid
	Evaluator:	Corporation	Over the wire	AngioJet Ultra	Free Sale Certificate
	Ms. Unum Zia	300, Boston Scientific	Thrombectomy	Console to	duly attested by
	Shamsi	Way, Marlborough,	Set	break apart	Embassy of
		MA 01752 USA	Class C	and remove	Pakistan.
		Manufacturing Site:	Codes:	thombus in	
		Boston Scientific	114610-001	peripheral	
		Corporation	08714729904724	vasculature.	
		Two Scimed Place,	A	Also intended	
		Maple Grove, MN	AngioJet <sup>™</sup>	for use with	
		USA 55311	ZelanteDVT™ Over-The-Wire	the AngioJet Ultra Power	
		(FSC LICEDA avairad	Thrombectomy	Pulse <sup>TM</sup>	
		(FSC US FDA expired on 26-06-2019)	Set	technique for	
		011 20-00-2017)	114610-002	the controlled	
			08714729904731	and selective	
				infusion of	
			AngioJet™	physician	
			ZelanteDVT™	specified	
			Over-The-Wire	fluids,	
			Thrombectomy	including	
			Set	thrombolytic	
			Shelf life: 24	agents, into the	
			Months	peripheral	
			Fee Submitted:	vascular	
			Rs: 50,000/-	system. Not to	
				be used in treatment of	
				pulmonary	
1				punnonary	

184	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	Магvel <sup>тм</sup> 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- H74939301300J2 08714729881209 Marvel Guidewire 300cm, J-tip Shelf life: 3 years Fee submitted: Rs. 50,000/-	embolism, and in coronary or cerebral or carotid vasculature 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.
	<b>Evaluator:</b> Ms. Unum Zia Shamsi	Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA	Monorail <sup>™</sup> Thrombectomy Set	apart and removing thrombus from infra-inguinal	

			Class D	peripheral	
			Class D	arteries. Not to	
		Manufacturing Site:	0.1		
		Boston Scientific	Codes:	be used for	
		Corporation	106553-002	treatment of	
		Two Scimed Place,	106553-003	pulmonary	
		Maple Grove, MN	106553-004	embolism and	
		USA 55311	106553-005	in	
			106553-006	carotid/cerebr	
		(FSC Ireland valid till	106553-007	al vasculature,	
		05-03-2023)		coronary	
		, ,	Shelf Life: 24	vasculature.	
			Months		
			Fee submitted:		
			Rs. 50,000/-		
186	-do-	Legal Manufacturer:	ChoICE™	Intended to	Approved.
100		Boston Scientific	Magnet	facilitate the	
	Evaluator:	Corporation, 300	Guidewire with	placement of	
	Ms. Unum Zia	Boston Scientific Way,	ICE <sup>TM</sup>	balloon	
	Shamsi	Marlborough, MA.	Hydrophilic	dilatation	
	511411151	01752 USA.	Coating	catheters or	
		01752 054.	Coating	other	
		Manufacturing site:	Class D		
		Manufacturing site: Boston Scientific	Class D	therapeutic	
			0.1	devices during	
		Corporation, 302	Codes:	PTCA or other	
		Parkway, Global Park	H7491213201M2	intravascular	
		La Aurora, Heredia,	08714729877103	interventional	
		Costa Rica.		procedures.	
			0.014", 182cm,	Not intended	
		(FSC US FDA valid	Straight, 5pk	for use in the	
		till 05-08-2020)		cerebral	
			H7491213201MJ	vasculature.	
			2		
			08714729877110		
			0.014", 182cm, J		
			Tip, 5pk		
			H7491213501M2		
			08714729877165		
			0.014", 182cm,		
			Straight, 5pk		
			H7491213501MJ		
			2		
			08714729877172		
			0.014", 182cm, J		
			Tip, 5pk		
			r, r		
			H7491213301M2		
			08714729877127		
		1		1	۱ <u> </u>

Evaluator: Ms. Unum Zia ShamsiBoston Scientific Corporation, 300Unidirectional Steerabletemp in DiagnosticBoston Scientific Way, Marlborough, MA.Diagnostic Catheterelect gy st Intra Codes:Manufacturing Site: Boston ScientificMo047000D0 08714729270133(pac of elect	l					
Evaluator: Ms. Unum Zia ShamsiBoston Scientific Corporation, 300Unidirectional Steerabletemp in DiagnosticMs. Unum Zia ShamsiBoston Scientific Way, Marlborough, MA. 01752 USA.Diagnostic Catheterelect gy st CatheterManufacturing Site: Boston ScientificManufacturing Site: 08714729270133Mo047000D0 of elect codes:(pact parkway, Global Park Heredia, Costa Rica.				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		
10-11-2020)Curve/Decapolar 6F/STD/2.5MM /105CM) M0047001D0 08714729270140 Unidirectional Steerable Diagnostic Catheter (Standard Curve/Decapolar 6F/STD/5MM/1 05CM) M0047003D0 08714729270164	H N	<b>Evaluator:</b> Ms. Unum Zia	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	Polaris $X^{TM}$ 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/1 05CM) M0047003D0	Intended for temporary use in electrophysiolo gy studies for intracardiac stimulation (pacing) and /or recording of electrical potentials.	Approved.

			Unidirectional		]
			Steerable		
			Diagnostic		
			Catheter (Standard		
			(Standard Curve/Decapolar		
			6F/STD/2.5/5/2		
			.5MM/105CM)		
			M0047004D0		
			08714729270171		
			Unidirectional		
			Steerable		
			Diagnostic		
			Catheter		
			(Standard		
			Curve/Decapolar 6F/STD/2-8-		
			6F/STD/2-8- 2MM/105CM)		
			2101101/105C101)		
			M0047005D0		
			08714729270188		
			Unidirectional		
			Steerable		
			Diagnostic Catheter		
			(Standard		
			Curve/Decapolar		
			6F/STD/2-10-		
			2MM/105CM)		
			Shelf Life: 2		
			Years		
			Fee submitted:		
188	-do-	Legal Manufacturer:	Rs. 50,000/- Blazer II XP	Therapeutic,	Approved.
100	-40-	Boston Scientific	Temperature	temperature-	Appioveu.
	Evaluator:	Corporation, 300	Ablation Catheter	controlled,	
	Ms. Unum Zia	Boston Scientific Way,	Class D	cardiac	
	Shamsi	Marlborough, MA.	Codes:	ablation	
		01752 USA.	M004EPT4500T	catheters	
			HK20	designed for	
		Manufacturing Site:	08714729268406	use in	
		Boston Scientific Corporation, 302	Temperature Ablation Catheter	intracardiac ablation,	
		Parkway, Global Park	(Large Curve/Std	mapping and	
		Heredia, Costa Rica.	Distal)	pacing.	
		(FSC Ireland valid till	M004EPT4500T	Delivers power	
		10-11-2020)	HN40	upto 150W.	
			08714729268437		
			Temperature		
			Ablation Catheter		
			(Asymmetric N4 Curve/Std Distal)		
				1	

r	
	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)
	N4004EDT4700T
	M004EPT4790T
	H0
	08714729268444
	Temperature Ablation Catheter
	Ablation Catheter
	(Standard Curve/Std Distal)
	M004EPT4500T0
	W1004EF 1450010
	08714729335313
	Temperature Ablation Catheter
	(Standard
	Curve/Std Distal)
	M004EPT4500T
	K20
	08714729335337
	Temperature
	Ablation Catheter
	(Large Curve/Std
	Distal)
	M004EPT4500T
	N40
	08714729335382
	Temperature
	Ablation Catheter
	(Asymmetric N4
	Curve/Std Distal)

				Г	·
			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-	Legal Manufacturer:	Blazer Prime XP	Blazer	Approved subject
		Boston Scientific	Temperature	Ablation	to provision of
	<b>Evaluator:</b>	Corporation 300,	Ablation	Catheter are	updated Letter of
	Shahid	Boston Scientific Way,	Cathether	intended to be	Authorization.
	Muhammad	Marlborough, MA.		used as a part	
	Iqbal	01752 USA.	(Codes & Sizes	of Boston	
	-	Manufacturing Site:	As per FSC)	Scientific	
		Boston Scientific	Class D	Corporation's	
		Corporation, 302	Shelf Life: 36	Cardiac	
					1
1		Parkway, Global Park,	Months	Ablation	

191	-do- <b>Evaluator:</b> 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:M004EPTP 5031TH0 GTIN: 08714729786320	ventricular response to an atrial arrhythmia. Blazer Prime Catheters are intended to be used as a part of Boston Scientific Corporation's Cardiac Ablation System. The	<b>Approved</b> subject to provision of updated Letter of Authorization.
190	-do- <b>Evaluator:</b> Shahid Muhammad Iqbal	Heredia, Costa Rica. FSC Ireland Valid till 10-11-2020	Rs.50,000/- Blazer II HTD Temperature Ablation Catheter (Codes & Sizes As per FSC) Class D Shelf Life: 36 Months Rs.50,000/-	Systems. The Commercially released system is indicated for interruption of accessory artioventricula r conduction pathways associated with Tachycardia. The Boston Scientific Cardiac Ablation systems is indicated for use for interruption of accessory atrioventricula r conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia and for creation of complete AV block in patients with a rapid	Approved subject to provision of updated Letter of Authorization.

		Hanadia Casta D'	Tomore		
		Heredia, Costa Rica.	Temperature	commercially	
			ablation Catheter	released	
		FSC Ireland	(Standard	system is	
		Valid till 10-11-2020	Curve).	indicated for	
				interruption of	
			UPN:M004EPTP	accessory	
			5031THK20	atrioventricula	
			GTIN:087147297	r Conduction	
				pathways	
			86337	associated	
			Temperature		
			ablation Catheter	with	
			(Large Curve).	tachycardia,	
				ventricular	
			UPN:M004EPTP	Tachycardia,	
			5031THN40	atrial Flutter,	
			GTIN:087147297	atrial	
				tachycardia	
			86344	and for	
			Temperature	creation of	
			ablation Catheter	complete Av	
			(Asymmetric	block in	
			Curve).		
			,	patients with	
			Class D	rapid	
				ventricular	
			Shelf Life: 36	response to an	
				atrial	
			Months	arrhythmia-	
			Rs.50,000/-	typically	
				chronic, drug	
				refactory atrial	
				fibrillation.	
102	40	Lagal Manufastruar	Dlagar II		A none of autoinst
192	-do-	Legal Manufacturer:	Blazer II	The Boston	Approved subject
		Boston Scientific	Temperature	Scientific	to provision of
	<b>Evaluator:</b>	Corporation 300,	Ablation	Cardiac	updated Letter of
	Shahid	Boston Scientific Way,	Catheter	Ablation	Authorization.
	Muhammad	Marlborough, MA.	(Codes & Sizes	Systems is	
	Iqbal	01752 USA.	As per FSC)	indicated for	
	-	Manufacturing Site:	Class D	use for	
		Boston Scientific	Shelf Life: 36	interruption of	
		Corporation, 302	Months	accessory	
		Parkway, Global Park,	Rs.50,000/-	atrioventricula	
		Heredia, Costa Rica.	1.3.30,000/-	r conduction	
		TICICUIA, CUSIA NICA.		pathways	
		ECO Instant			
		FSC Ireland		associated	
		Valid till 10-11-2020		with	
				tachycardia,	
				for treatment	
				of Av nodal	
				reentranttac;yc	
				ardia and for	
				creation of	
				completer Av	
		I		compicter Av	1

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				block in	
				patient with a	
				rapid	
				ventricular	
				response to an	
				atrial	
				arrhythmia-	
				typically	
				chronic, drug	
				refactory atrial	
				fabrillation.	
193	-do-	Legal Manufacturer:	Blazer Open-	Blazer Open-	Approved subject
170		Boston Scientific	Irrigated	Irrigated	to provision of
	Evaluator:	Corporation 300,	Ablation	Ablation	updated Letter of
	Shahid	Boston Scientific Way,	Catheter	Catheter is	Authorization.
	Muhammad			indicated for	Aumonzanon.
		Marlborough, MA.	UPN:		
	Iqbal	01752 USA.	M004EPT96200	use in catheter	
			GTIN:	-based cardiac	
		Manufacturing Site:	08714729792925	electrophysiolo	
		Boston Scientific	Ablation Catheter	gical mapping	
		Corporation, 302	(Standard Curve)	(stimulating	
		Parkway, Global Park,	UPN:M004EPT9	and recording)	
		Heredia, Costa Rica.	620K20	and, when	
			GTIN:087147297	used in	
		FSC Ireland	92932	conjunction	
		Valid till 10-11-2020	Ablation Catheter	with a	
			(Large Curve)	radiofrequency	
			UPN:M004EPT9	generator, for	
			620N40	cardiac	
			GTIN:087147297	ablation.	
			92956		
			Ablation Catheter		
			(Asymemetric		
			Curve)		
			UPN:M004EPT9		
			620K2E0		
			GTIN:087147297		
			92963		
			Ablation Catheter		
			(Large Curve/		
			Extra Long)		
			Class D		
			Shelf Life: 36		
			Months		
			Rs.50,000/-		
194	-do-	Legal Manufacturer:	Radia	The Steerable	Approved subject
		Boston Scientific	Bidirectional	diagnostic	to provision of
	Evaluator:	Corporation 300,	Steerable	electrode	updated Letter of
	Shahid	Boston Scientific Way,	Diagnostic	catheter is	Authorization.
	Muhammad	Marlborough, MA.	Catheter	intended for	
	Iqbal	01752 USA.	(Codes & Sizes	temporary	
	-1001		•		1
I I		Manufacturing Site:	As per FSC)	intracardiac	

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

				of cardiac	
				arrhythmias.	
198	-do- <b>Evaluator:</b> 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.	<b>Approved</b> subject to provision of updated Letter of Authorization.
199	-do- <b>Evaluator:</b> 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 <sup>TM</sup> Microcatheter MAMBA <sup>TM</sup> MicroCatheter MAMBA 135 cm (OUS) H7493928713520 Class D Shelf Life: 2 Years Rs.50,000/-	Peripheral /coronary vascular microcatheter	<b>Approved</b> subject to provision of updated Letter of Authorization.
200	-do- <b>Evaluator:</b> 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 <sup>TM</sup> 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 cmm hangth	<b>Approved</b> as class- D medical devicesubject to provision of updated Letter of Authorization.
201	-do-	<b>Legal Manufacturer:</b> Boston Scientific	Direxion <sup>™</sup> Torqueable	cm in length The Direxionand	<b>Approved</b> subject to provision of

	<b>Evaluator:</b> Shahid Muhammad Iqbal	Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. <b>Manufacturing Site:</b> 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	updated Letter of Authorization.
202	40	Lagal Manufacturar	Diantinum Dius <sup>TM</sup>	microcatheter in the peripheral vasculatre.	Approved subject
202	-do- <b>Evaluator:</b> 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 <sup>™</sup> 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.	<b>Approved</b> subject to provision of updated Letter of Authorization.
203	-do- <b>Evaluator:</b> 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 <sup>™</sup> 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 WATCHMA N Access System is intended to provide vascular and transseptal access for the WATCHMA N 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-	Legal Manufacturer:	WATCHMAN <sup>TM</sup>	The	Approved subject
		Boston Scientific	Left Artial	Watchman	to provision of
	Evaluator:	Corporation 300,	Appendage	LAA closure	updated Letter of
	Shahid Muhammad	Boston Scientific Way, Marlborough, MA.	Closure Device	Technology is intended to	Authorization.
	Iqbal	01752 USA.	with Delivery System	prevent	
	iquu		M635WS21060	thrombus	
		Manufacturing Site:	21mm	embolization	
		Boston Scientific	WATCHMAN	from the left	
		Limited, Ballybrit	LAA	atrial	
		Business Park,	Closure/Deliver	appendage and reduce the risk	
		Galway, Ireland.	y, 12F M635WS24060	of life-	
		FSC Ireland	24mm	threatening	
		Valid till 12-04-2023	WATCHMAN	bleeding events	
			LAA	in patients	
			Closure/Deliver	with non-	
			y, 12F	valvular atrial fibrillation	
				who are	
			M635WS27060	eligible for	
			27mm WATCHMAN	anticoagulatio	
			LAA	n therapy or	
			Closure/Deliver	who have a	
			y, 12F	contraindicatio	
			M635WS30060	n to anticoagulatio	
			30mm	n therapy.	
			WATCHMAN		
			LAA		
			Closure/Deliver		
			y, 12F M635WS33060		
			33mm		
			WATCHMAN		
			LAA		
			Closure/Deliver		
			y, 12F		
			Class D		
			Shelf life: 36 Months		
			Rs.50,000/-		
205	-do-	Legal Manufacturer:	ELUVIA <sup>TM</sup> Over-	The ELUVIA	Approved subject
		Boston Scientific	The-Wire Drug-	Drug Eluting	to provision of
	<b>Evaluator:</b>	Corporation 300,	Eluting Vascular	Vascular Stent	updated Letter of
	Shahid	Boston Scientific Way,	Stent System	System is	Authorization.
	Muhammad	Marlborough, MA.		intended to	

	Iqbal	01752 USA. <b>Manufacturing Site:</b> 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- <b>Evaluator:</b> 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 <sup>™</sup> 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.	<b>Approved</b> subject to provision of updated Letter of Authorization.
207	-do- <b>Evaluator:</b> 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 <sup>TM</sup> CoAccess <sup>TM</sup> 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	<b>Approved</b> subject to provision of updated Letter of Authorization.

208	-do- <b>Evaluator:</b> 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 26 <sup>th</sup> March , 2021	LeVeen CoAccess Electrode System 4.0cm x 15cm Class C Shelf life: 36 Months Rs.50,000/- Hornet TM Guidewire H749393051902 08714729886655 Hornet Guidewire 190cm, Straight- tip H749393053002 08714729886662 Hornet Guidewire 300cm, Straight- tip Class D Shelf life: 3years Rs.50,000/-	partial or complete ablation of nonres ectable liver lesions. 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- <b>Evaluator:</b> 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 TM , Marvel TM , Samurai TM and Samurai TM Rc Duidewires are intended to facilitate the placement of balloon dilatation	<b>Approved</b> subject to provision of updated Letter of Authorization.

	40	FSC USA Valid till 26 <sup>th</sup> 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 4 <sup>th</sup> January,2023	Wolverine ™CoronaryCutting Balloon™ MONORAIL™ MicrosurgicalDilatationDeviceH7493940306200OWolverineCutting BalloonMR, OUS6mmx2.0mmH7493940306225OWolverineCutting BalloonMR, OUS6mmx2.25mmH74939403062500 WolverineCutting BalloonMR, OUS6mmx2.50mmH7493940306275OWolverineCutting BalloonMR, OUS6mmx2.75mmH7493940306300OWolverineCutting BalloonMR, OUS6mmx2.75mmH7493940306300OWolverineCutting BalloonMR, OUS6mmx2.75mmH7493940306300OWolverineCutting BalloonMR, OUS6mmx3.00mm	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
OWolverine
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
10mmx4.00mm
115 (020 (021 5200
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
8
,
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

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

 Classies :	Deulerer Old ID 1	Terrer	1	
Shamsi	Parkway, Global Park	Temperature	mapping and	
	Heredia, Costa Rica.	Ablation Catheter	pacing.	
		(Large Curve/Std	Delivers power	
	(FSC Ireland valid till	Distal)	upto 150W.	
	10-11-2020)			
		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		
	•	•		·

r		
	(Standard Curve/Std Dis	tal)
	M004EPT4500 K20 087147293353 Temperature Ablation Catho (Large Curve/ Distal)	37 eter
	M004EPT4500 N40 087147293353 Temperature Ablation Catho (Asymmetric N Curve/Std Dis	82 eter V4
	M004EPT4500 MK20 087147293353 Temperature Ablation Catho (Large Curve/Med Distal)	68
	M004EPT4790 K20 087147293354 Temperature Ablation Catho (Large Curve/ Distal)	98 eter
	M004EPT4790 HK20 087147292684 Temperature Ablation Catho (Large Curve/ Distal)	51 eter
	M004EPT4790 HM0 087147292684 Temperature Ablation Catho (Standard Curve/Med Distal)	68

		Γ			1
			M004EPT4790T HMK20 08714729268475 Temperature Ablation Catheter (Large Curve/Med Distal) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-		
213	-do- <b>Evaluator:</b> 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 nasopharyngea 1 (NP) swab and nasal swab (NS) specimens.	Approved.
214	-do- <b>Evaluator:</b> 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	[]
				the diagnosis	
				of H.pylori	
				infection in an	
				adult	
				symptomatic	
				population.	
215	-do-	Legal Manufacturer:	VIDAS® HAV	An automated,	Approved.
		BioMérieux SA	IgM Test Kit	qualitative test	
	<b>Evaluator:</b>	376 Chemin de l'Orme		for use on the	
	Ms. Unum Zia	69280 Marcy l'Etoile –	Class C	VIDAS family	
	Shamsi	France.		instruments for	
			Codes:	the detection	
		Manufacturing Site:	VIDAS® HAV	of IgM	
		BioMérieux SA	IgM	directed	
		376 Chemin de l'Orme	Ref. 30307	against the	
		69280 Marcy l'Etoile -	30 Tests	hepatitis A	
		France.		virus (HAV)	
			Shelf Life: 11	after	
		FSC France issued on	months	immunocaptur	
		13.12.2017		e, in human	
			Fee submitted:	serum or	
			Rs. 25,000/-	plasma	
			103. 20,0007	(heparin or	
				EDTA), using	
				the ELFA	
				technique	
				(Enzyme	
				Linked	
				Fluorescent	
01/	1			Assay).	
216	-do-	Legal Manufacturer:	VIDAS® PTH (1-	A third-	Approved.
	<b>T 1</b>	BioMérieux SA	84) Test Kit	generation	
	Evaluator:	376 Chemin de l'Orme	Class B	automated	
	Ms. Unum Zia	69280 Marcy l'Etoile –	Codes:	quantitative	
	Shamsi	France.	VIDAS® PTH (1-	assay for use	
			84)	on the VIDAS	
		Manufacturing Site:	Ref. 422010	family of	
		BioMérieux SA	30 Tests	instruments for	
		376 Chemin de l'Orme	Shelf Life: 12	the	
		69280 Marcy l'Etoile –	months	quantitative	
		France.	Fee submitted:	measurement	
			Rs. 25,000/-	of the	
		FSC France issued on		biologically	
		20-12-2018		active	
				parathyroid	
				hormone in	
				human serum	
				or plasma	
				using the	
				ELFA	
				(Enzyme	
				Linked	
					1

				Fluorescent	
				Assay)	
				technique.	
217	-do-	Legal Manufacturer:	VITEK® 2 AST	icennique.	Deferred due to
21/	-40-	BioMerieux, Inc. 100	Cards		
			Carus		cluster applications.
	Evaluator:	Rodolphe Street,			
	Ms. Unum Zia	Durham, North	Class B		
	Shamsi	Carolina, 27712, USA			
		Manufacturing site:	Codes:	Gram	
		BioMerieux, Inc. 595	Vitek 2 AST-	Negative	
		Anglum Road,	XN05	Susceptibility	
		Hazelwood, Missouri	Ref No: 413230	Card intended	
		63042	Shelf Life: 548	to determine	
			days	the	
		FSC France issued on	Contents: SAM,	susceptibility	
		25-07-2018	ATM, FEP,	of clinically	
1			CFM, CRO,	significant	
1			CXM, C, CS,	aerobic gram-	
			ESB, LEV,	negative bacilli	
1			MEM, MNO,	to	
			MXF, PIP, TE,	antimicrobial	
1			TCC, TGC, TMP	agents	
1			No. of Cards: 20		
			Cards	Gram	
			Vitek 2 AST-	Negative	
			GN81	Susceptibility	
			Ref No: 413438	Card intended	
			Shelf Life: 548	to determine	
			days	the	
			Contents: AN,	susceptibility	
			AMC, AM, CZ,	of clinically	
			FEP, FOX, CAZ,	significant	
			CRO, CIP, ETP,	aerobic gram-	
			GM, LEV,	negative bacilli	
			MEM, FT, TZP,	to	
			TE, TM, SXT	antimicrobial	
			No. of Cards: 20	agents	
1			Cards		
1					
1			Vitek 2 AST-	Gram	
			GN84	Negative	
1			Ref No: 413410	Susceptibility	
1			Shelf Life: 548	Card intended	
1			days	to determine	
			Contents: AMC,	the	
			AM, ATM, CZ,	susceptibility	
			FEP, CRO, CIP,	of clinically	
			ETP, ESB, GM,	significant	
			IPM, LEV,	aerobic gram-	
			MEM, FT, TZP,	negative bacilli	
			TE, SXT	to	
L		1			l

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

1	
Contents: AN,	Card intended
ATM, FEP,	to determine
CAZ, CIP, CS,	the
GM, IPM, MEM,	
	susceptibility
MNO, PEF, PIP,	of clinically
TZP, RA, TIC,	significant
TCC, TM, SXT	aerobic gram-
No. of Cards: 20	negative bacilli
Cards	to
Calus	
	antimicrobial
Vitek 2 AST-	agents
N235	
Ref No: 413170	
Shelf Life: 548	Gram
	Negative
days	
Contents: AN,	Susceptibility
AMC, AM, CF,	Card intended
CFM, FOX,	to determine
CAZ, CRO, CIP,	the
ETP, FOS, GM,	susceptibility
NA, FT, NOR,	of clinically
OFL, TZP, TIC,	significant
SXT	aerobic gram-
No. of Cards: 20	negative bacilli
Cards	to
Carus	antimicrobial
Vitek 2 AST-	agents
N374	
Ref No: 423008	
Shelf Life: 548	Gram
	Negative
days	
Contents: AN,	Susceptibility
AMC, AM, FEP,	Card intended
CTX, CAZ,	to determine
CXM, CIP, ETP,	the
ESB, GM, IPM,	susceptibility
	of clinically
MEM, TZP, SXT	
No. of Cards: 20	significant
Cards	aerobic gram-
	negative bacilli
Vitek 2 AST-	to
P580	antimicrobial
Ref No: 22233	agents.
	ugento.
Shelf Life: 548	
days	
Contents: P,	Gram Positive
OXSF, CM, E,	Susceptibility
FOS, FA, GM,	Card intended
	to determine
ICR, LEV, LNZ,	
MXF, MUP, FT,	the
OX1, RA, TEC,	susceptibility
TE, TGC, TM,	of

		1 1
		aphylococcu
		pp.,
	Cards En	terococcus
	spr	p., and S.
		alactiae to
	Ũ	timicrobial
	Ũ	ents.
	Shelf Life: 548	
		ram Positive
	, ,	sceptibility
	OXSF, CIP, CM, Ca	rd intended
	E, FOS, FA, GM, to c	determine
	HLG, IPM, ICR, the	
		sceptibility
	OX1, RA, HLS, of	
	;;	aphylococcu
	, , , ,	- •
		pp.,
		iterococcus
		p., and S.
	0	alactiae to
	Vitek 2 AST- ant	timicrobial
	YS05 age	ents.
	Ref No: 411945	
		ıngal
		sceptibility
		urd intended
	,	determine
	,	
	No. of Cards: 20 the	
		sceptibility
		clinically
	Vitek 2 AST- sig	nificant
	<b>YS07</b> yea	asts to
	Ref No: 414967 ant	tifungal
		ents
	days	
	Contents: AB, Fu	ıngal
	,	sceptibility
	, , , , , , , , , , , , , , , , , , , ,	urd intended
		determine
	110. 61 Cuius. 20	
	Cards the	
		sceptibility
	· · · · · ·	clinically
	1000 0	nificant
	Ref No: 420739 yea	asts to
		tifungal
		ents
	Contents: AB,	
		ıngal
		sceptibility
	,	ard intended
	110. 01 Culub. 20	
	Curub	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	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,	
			Rs. 25,000/-	beta-hemolytic Streptococcus, and Viridans Streptococcus to antimicrobial agents	
218	-do-	Legal Manufacturer	VIDAS Cortisol S	VIDAS	Approved subject
	<u>Evaluator</u> : Shahid Muhammad Iqbal	and Manufacturing Site: BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France.	VIDAS Cortisol S 30451 Class B Shelf Life: 7 months	Cortisol S is an automated quantitative test for use on the VIDAS family instruments, for the	to provision of updated LOA, FQA or explanation from manufacturer.
		FSC France Issued on 13.12.2017	Rs.25,000/-	quantitative determination of cortisol in human serum,	

				n1	
				plasma	
				(lithium	
				heparin or	
				EDTA) or	
				urine using the	
				ELFA	
				technique.	
219	-do-	Legal Manufacturer	VIDAS®	VIDAS	Approved subject
		and Manufacturing	TOTAL IgE	TOTAL IgE is	to provision of
	Evaluator:	Site:		an automated	updated LOA,
	Shahid	BioMérieux SA	<b>VIDAS</b> ®	quantitative	FQA or explanation
	Muhammad	376 chemin de l'Orme	TOTAL IgE	test for use on	from manufacturer.
	Iqbal	69280 Marcy l'Etoile –	30419	the VIDAS	
	-	France.		family	
			Class B	instruments,	
				for the	
		FSC France	Shelf Life: 12	immune	
		Issued on 13.12.2017	months	enzymatic	
				determination	
			Rs.25,000/-	of total human	
				IgE in human	
				serum or	
				plasma	
				(lithium	
				heparin or	
				EDTA) using	
				the ELFA	
				technique.	
220	-do-	Legal Manufacturer	VIDAS® Ferritin	VIDAS	Approved subject
_		and Manufacturing		Ferritin is an	to provision of
	<b>Evaluator:</b>	Site:	VIDAS® Ferritin	automated	updated LOA,
	Shahid	BioMérieux SA	30411	quantitative	FQA or explanation
	Muhammad	376 chemin de l'Orme		test for use on	from manufacturer.
	Iqbal	69280 Marcy l'Etoile –	Class B	the VIDAS	nom manalactarer.
	iquui	France.	Class D	family	
			Shelf Life: 12	instruments for	
		FSC France	months	the	
		Issued on 13.12.2017	montils	determination	
		135464 011 15.12.2017	Rs.25,000/-	of human	
			10.20,0007	Ferritin in	
				human serum	
				or plasma	
				(lithium	
				heparin or	
				EDTA) using	
				the ELFA	
				technique.	
221	-do-	Legal Manufactuer:	SaMag Viral	SaMag Viral	Approved.
	40	1.20 m 1.1 m 1 m 1 m 1 m 1 m 1 m 1 m 1 m 1 m	Nucleic Acid	Nucleic Acids	·
	<b>F</b> 1	M/s. Sacace	Extraction Kit	Extraction Kit	
	Evaluator				
	<u>Evaluator</u> : Hafiz				
	<u>Evaluator</u> : Hafiz Muhammad	Biotechnologies s.r.l. via Santisi snc- 80024-	(Viral Nucleic Acid Extraction	is designed to be used with	

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

			00445.10	374374	
			22445-19	NAV6	
		FSC Belgium issued	BareWire FTW,	Embolic	
		on 26-04-2019	Workshorse,	Protection	
			315cm	System	
			22445-31	-	
			BareWire FTW,		
			Support, 190cm		
			22446-19		
			Shelf Life: 03		
			years		
			Fee submitted:		
			Rs. 50,000/-	T 1 1 1 C	
225	-do-		Supera Peripheral	Indicated for	Approved.
		Legal Manufacturer:	Stent System	peripheral	
	Evaluator:	Abbot Vascular, 3200		vascular use	
	Ms. Unum Zia	Lakeside Drive, Santa		following	
	Shamsi	Clara, Falifornia, USA	Class C	failed	
		,	Codes:	percutaneous	
		Manufacturer Site:	42045020-080	transluminal	
		Abbot Vascular	42045030-080	angioplasty	
		Temecula 26531 Ynez	42045040-080	(PTA) and	
		Road Temecula,	42045060-080	palliative	
		California 92591, USA	42045080-080	treatment of	
		Camornia 72571, USA	42045100-080	biliary	
		ESC Dalaina internal		strictures	
		FSC Belgium issued	42045120-080	produced by	
		on 02-05-2019	42045150-080	malignant	
			42055020-080	neoplasms.	
			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		
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			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		Brilliant	Intended for	Approved.
	CorporationOf	Manufacturer:	Introducer Kit	use to facilitate	TIT
	fice No. 30,	Lepu Medical	Class B	the	
	First Floor, Al-	Technology (Beijing)	Codes as per FSC	introduction of	
	Amin Plaza,	Co., Ltd	Netherlands	guidewires,	
	The Mall	No. 37 Chaoqian	dated Nov 7,	catheters and	
	Rawalpindi.	Road, Changping	2019. Certificate	other accessory	
	ELI- 00034	District, Beijing,	No. 26075	medical	
	ELI- 00034 Evaluator:		Shelf Life 03	devices	
		102200, China			
	Ms. Unum Zia	ECO Mathematica 111	years	through the	
	Shamsi	FSC Netherlands valid	Fee submitted:	skin into vein	
		till23 June 2020	Rs. 25,000/-	or artery and	
				minimize	

				blood loss	
				associated with	
				such	
				introduction	
227	-do-	Manufacturer:	Lepu Medical-	Indicated to	Approved.
		Lepu Medical	Contrast	provide	
	<b>Evaluator:</b>	Technology (Beijing)	Medium	injection	
	Ms. Unum Zia	Co., Ltd	Injection	channel for	
	Shamsi	No. 37 Chaoqian	Manifold Kits	fluid and	
		Road, Changping	Class B	contrast	
		District, Beijing,	Codes:	transportation	
		102200, China	MK-001- MK-	in	
			002-MK-003-	interventional	
			MK-004-	operation.	
		FSC Netherlands valid	MK-005- MK-		
		till23 June 2020	006-MK-013-		
			MK-014- MK-015- MK-		
			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:		
220		M	Rs. 25,000/-	To directe d form	A
228	-do- Evaluator:	Manufacturer: Lepu Medical	SHOOCIN INTRODUCER	Indicated for use in arterial	Approved.
	Ms. Unum Zia	Technology (Beijing)	KIT	procedures	
	Shamsi	Co., Ltd	Class B	requiring	
	Gilailioi	No. 37 Chaoqian	Codes as per FSC	percutaneous	
		Road, Changping	Netherlands	introduction of	
		District, Beijing,	dated Nov 7,	intravascular	
		102200, China	2019 Certificate	devices	
			No. 26075		
		FSC Netherlands valid	Shelf Life: 03		
		till23 June 2020	years		
			Fee submitted:		
		2.5	Rs. 25,000/-		
229	-do-	Manufacturer:	Lepu Medical-	Indicated for	Approved.
	F 1. 4	Lepu Medical	Inflation Device	use in PCI to	
	Evaluator:	Technology (Beijing)	Kit	provide the	
	Ms. Unum Zia	Co., Ltd	LP-P-30-YNP	pressure inside balloon	
	Shamsi	No. 37 Chaoqian Road, Changping	LP-P-30S-YNP LP-P-30-YNR	Janoon	
		District, Beijing,	LP-P-30S-YNR		
		District, Deljing,	TT -1 -2002-1111/		

r r	100000 01:		
	102200, China	LP-P-30-YNP20	
		LP-P-30S-YNP20	
		LP-P-30-YNP25	
	FSC Netherlands valid	LP-P-30S-YNP25	
	till	LP-P-30-YNP40	
	23 June 2020	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	
		r-405-1 NP30H	 <u> </u>

Class B	
Shelf Life: 03	
years	
Fee submitted:	
Rs. 25,000/-	
230 -do- Manufacturer: <b>CP Stent</b> (Sterile CP stent (	bare) Approved.
NuMED, Inc. Cheatham is indicated	
<b>Evaluator:</b> 2880 Main Street Platinum Stent) implantation	
/ 1	
1 /	allve
Shamsi 12965, USA Codes: and/or	
CP8Z16, recurrent	
FSC USA FDA valid CP8Z22, coarctation	n of
till 20.05.2021 CP8Z28, the aorta.	
CP8Z34,	
CP8Z39,	
CP8Z45,	
CP8Z50,	
CP8Z55,	
CP8Z60,	
CP10Z39,	
CP10Z45,	
CP10243, CP10Z50,	
,	
CP10Z55,	
CP10Z60	
Shelf life 5 years	
Fee submitted:	
Rs. 50,000/-	
231 -do- BIB® Stent Indicated f	for Approved.
Manufacturer: Placement stent	
<b>Evaluator:</b> NuMED, Inc. <b>Catheter</b> placement	in
Ms. Unum Zia 2880 Main Street vessels ove	er
Shamsi Hopkinton, NY Size Codes: 8mm in	
12965, USA BB003, BB006, diameter	
BB009, BB010,	
FSC USA FDA valid BB011, BB012,	
till 20.05.2021 BB013, BB014,	
BB015, BB016, BB017, BB018	
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,	
BB041, BB042, BB051, BB052,	
BB053, BB054,	

			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-		Covered CP	CP stent (bare)	Approved.
		Manufacturer:	Stent	is indicated for	
	Evaluator:	NuMED, Inc.	Class D	implantation	
	Ms. Unum Zia	2880 Main Street	Codes:	in the native	
	Shamsi	Hopkinton, NY	CVRDCP8Z16,	and/or	
		12965, USA	CVRDCP8Z22,	recurrent	
			CVRDCP8Z28,	coarctation of	
		FSC USA FDA valid	CVRDCP8Z34,	the aorta and	
		till 20.05.2021	CVRDCP8Z39,	to maintain	
			CVRDCP8Z45,	right	
			CVRDCP8Z50,	ventricular	
			CVRDCP8Z55,	outflow tract	
			CVRDCP8Z60,		
			CVRDCP10Z39,		
			CVRDCP10Z45,		
			CVRDCP10Z50,		
			CVRDCP10Z55,		
			CVRDCP10Z60.		
			Shelf life: 05 years		
			Fee submitted: Rs. 50,000/-		
233	-do-	Manufacturer:	PTS-X <sup>TM</sup> Sizing	Used in those	Approved.
200	-40-	NuMED Canada Inc.	Balloon Catheter	patients with	Approveu.
	Evaluator:	45 Second Street West	Class D	cardiovascular	
	Ms. Unum Zia	Cornwall ON K6J	Codes:	defects	
	Shamsi	IG3, Canada.	PTSX101,	wherein	
			PTSX102,	accurate	
		FSC Canada issue date	PTSX103,	measurement	
		2-6-2019	PTSX104,	of the defect is	
			PTSX105,	important to	
			PTSX106,	select the	
			PTSX122,	appropriately	
			PTSX123,	sized occluder	
			PTSX124,	device.	
			PTSX125,		
1 1			PTSX152,	1	

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

PDCS07, • A patient PDC508, with valbular PDC509, pulmonary Stenosis with PDC510, stenosis with PDC511, other minor PDC512, congenital PDC513, theat disease that does not PDC514, require Surgical PDC516, surgical PDC516, intervention. PDC517, intervention. PDC518, PDC520, PDC521, PDC522, PDC522, PDC523, PDC524, PDC524, PDC525, PDC525, PDC523, PDC523, PDC523, PDC524, PDC524, PDC523, PDC523, PDC524, PDC523, PDC531, PDC533, PDC533, PDC534, PDC534, PDC534, PDC535, PDC535, PDC534, PDC544, PD		BD 0504		
PDC508,       with valvular         PDC509,       pulmonary         PDC511,       other minor         PDC512,       congenital         PDC513,       heart disease         PDC514,       that does not         PDC515,       surgical         PDC518,       pDC518,         PDC519,       pDC519,         PDC520,       PDC520,         PDC520,       PDC521,         PDC523,       PDC524,         PDC524,       PDC525,         PDC530,       PDC528,         PDC528,       PDC527,         PDC528,       PDC530,         PDC530,       PDC531,         PDC531,       PDC532,         PDC533,       PDC534,         PDC535,       PDC535,         PDC536,       PDC537,         PDC537,       PDC534,         PDC538,       PDC534,         PDC544,       PDC544,		PDC506,	stenosis.	
PDCS09,       pulmonary         PDCS10,       stenosis with         PDCS11,       other minor         PDCS12,       congenital         PDCS13,       theart disease         PDCS14,       tratidoes not         PDCS15,       surgical         PDCS16,       surgical         PDCS17,       intervention.         PDCS18,       PDCS20,         PDCS21,       PDCS23,         PDCS22,       PDCS23,         PDCS24,       PDCS24,         PDCS25,       PDCS26,         PDCS26,       PDCS27,         PDCS27,       PDCS28,         PDCS28,       PDCS31,         PDCS31,       PDCS33,         PDCS33,       PDCS33,         PDCS34,       PDCS34,         PDCS35,       PDCS36,         PDCS36,       PDCS36,         PDCS37,       PDCS36,         PDCS38,       PDCS36,         PDCS39,       PDCS36,         PDCS36,       PDCS36,         PDCS47,       PDCS44,         PDCS44,       PDCS44,         PDCS44,       PDCS44,         PDCS45,       PDCS46,         PDCS47,       PDCS48				
PDC510,       stenois with         PDC511,       other minor         other minor       congenital         PDC512,       heart disease         PDC513,       heart disease         PDC514,       that does not         PDC515,       sturgical         PDC517,       intervention.         PDC519,       PDC520,         PDC521,       PDC522,         PDC522,       PDC523,         PDC524,       PDC525,         PDC525,       PDC526,         PDC526,       PDC527,         PDC528,       PDC528,         PDC530,       PDC533,         PDC533,       PDC534,         PDC533,       PDC534,         PDC533,       PDC533,         PDC534,       PDC535,         PDC535,       PDC536,         PDC536,       PDC537,         PDC537,       PDC536,         PDC538,       PDC536,         PDC544,       PDC544,         PDC545,       PDC544,         PDC544,       PDC544,         PDC544,       PDC544,         PDC551,       PDC550,         PDC551,       PDC551,         PDC551,		PDC508,		
PDCS10,       stenois with         PDCS11,       other minor         PDCS12,       heart disease         PDCS13,       heart disease         PDCS14,       that does not         PDCS15,       surgical         PDCS16,       intervention.         PDCS17,       PDCS18,         PDC518,       PDCS20,         PDC520,       PDCS22,         PDC522,       PDCS23,         PDC524,       PDCS25,         PDC525,       PDC526,         PDC526,       PDC527,         PDC527,       PDC528,         PDC530,       PDC531,         PDC531,       PDC533,         PDC533,       PDC534,         PDC534,       PDC535,         PDC535,       PDC534,         PDC534,       PDC535,         PDC535,       PDC534,         PDC534,       PDC535,         PDC535,       PDC536,         PDC544,       PDC544,         PDC544,       PDC544,         PDC545,       PDC546,         PDC546,       PDC550,         PDC551,       PDC552,         PDC551,       PDC552,         PDC551,       PDC552,<		PDC509,		
PDCS11,       orgenital         PDCS12,       congenital         PDCS13,       that does not         PDCS14,       that does not         PDCS15,       surgical         PDCS16,       surgical         PDCS17,       intervention.         PDCS18,       PDCS20,         PDCS21,       PDCS21,         PDCS22,       PDCS22,         PDCS24,       PDCS25,         PDCS25,       PDCS26,         PDCS27,       PDCS28,         PDCS30,       PDCS31,         PDCS31,       PDCS32,         PDCS32,       PDCS33,         PDCS33,       PDCS34,         PDCS34,       PDCS35,         PDCS35,       PDCS34,         PDCS34,       PDCS34,         PDCS44,       PDCS44,         PDCS51,       PDCS52,         PDCS44,       PDCS44,				
PDC512, congenital PDC513, heart disease that does not PDC514, require Surgical intervention. PDC516, intervention. PDC517, PDC519, PDC520, PDC522, PDC522, PDC523, PDC525, PDC525, PDC525, PDC526, PDC527, PDC528, PDC533, PDC533, PDC533, PDC533, PDC534, PDC534, PDC535, PDC535, PDC535, PDC536, PDC537, PDC537, PDC537, PDC538, PDC538, PDC538, PDC538, PDC538, PDC539, PDC534, PDC534, PDC535, PDC536, PDC537, PDC537, PDC536, PDC537, PDC536, PDC537, PDC537, PDC538, PDC538, PDC538, PDC539, PDC544, PDC544, PDC544, PDC545, PDC544, PDC545, PDC544, PDC545, PDC544			other minor	
PDC513, that does not PDC514, require PDC516, surgical PDC516, intervention. PDC517, PDC518, PDC519, PDC520, PDC520, PDC521, PDC522, PDC522, PDC523, PDC524, PDC524, PDC525, PDC526, PDC528, PDC529, PDC530, PDC531, PDC532, PDC532, PDC534, PDC534, PDC535, PDC535, PDC536, PDC537, PDC536, PDC537, PDC538, PDC536, PDC537, PDC536, PDC537, PDC534, PDC534, PDC544, PDC544, PDC544, PDC544, PDC545, PDC545, PDC544, PDC544, PDC545, PDC546, PDC546, PDC547, PDC546, PDC546, PDC547, PDC546, P				
PDC514, that does not require PDC515, surgical intervention. PDC517, PDC518, PDC519, PDC520, PDC520, PDC520, PDC522, PDC522, PDC522, PDC523, PDC524, PDC525, PDC525, PDC528, PDC528, PDC528, PDC530, PDC531, PDC531, PDC533, PDC534, PDC534, PDC534, PDC535, PDC535, PDC536, PDC536, PDC537, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC538, PDC534, PDC536, PDC537, PDC538, PDC538, PDC538, PDC538, PDC534, PDC534, PDC542, PDC541, PDC542, PDC542, PDC542, PDC543, PDC544, PDC543, PDC544, PDC545, PDC545, PDC545, PDC548, PDC548, PDC548, PDC548, PDC548, PDC548, PDC548, PDC548, PDC548, PDC548, PDC549, PDC548, PDC548, PDC549, PDC549, PDC548, PDC549, PDC540, P				
PDC515, require surgical pDC516, surgical intervention. PDC518, PDC519, PDC520, PDC520, PDC521, PDC523, PDC524, PDC524, PDC525, PDC526, PDC526, PDC527, PDC526, PDC530, PDC530, PDC531, PDC533, PDC533, PDC533, PDC534, PDC534, PDC535, PDC534, PDC535, PDC534, PDC544, PDC544, PDC544, PDC544				
PDC516, PDC516, PDC517, PDC518, PDC519, PDC520, PDC521, PDC522, PDC522, PDC522, PDC523, PDC525, PDC525, PDC526, PDC527, PDC528, PDC530, PDC530, PDC531, PDC533, PDC535, PDC535, PDC536, PDC536, PDC537, PDC538, PDC538, PDC539, PDC539, PDC536, PDC536, PDC537, PDC538, PDC538, PDC538, PDC544, PDC542, PDC542, PDC544, PDC544, PDC545, PDC545, PDC544, PDC544, PDC545, PDC545, PDC545, PDC546, PDC547, PDC546, PDC547, PDC547, PDC548, PDC548, PDC549, PDC544, PDC544, PDC545, PDC545, PDC546, PDC545, PDC546, PDC547, PDC546, PDC547, PDC546, PDC547, PDC546, PDC547, PDC546, PDC547, PDC546, PDC547, PDC548, PDC548, PDC549, PDC549, PDC544, PDC544, PDC544, PDC545, PDC545, PDC546, PDC547, PDC546, PDC547, PDC548, PDC548, PDC549, PDC549, PDC540, PDC540, PDC540, PDC540, PDC540, PDC541, PDC540, PDC540, PDC540, PDC541, PDC540, PDC				
PDC517, intervention. PDC518, PDC519, PDC520, PDC520, PDC522, PDC522, PDC523, PDC525, PDC526, PDC526, PDC526, PDC528, PDC529, PDC530, PDC531, PDC533, PDC533, PDC534, PDC535, PDC535, PDC535, PDC536, PDC537, PDC538, PDC538, PDC537, PDC538, PDC534, PDC534, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC544, PDC545, PDC546, PDC546, PDC547, PDC546, PDC547, PDC548, PDC548, PDC549, PDC548, PDC552, S0001,S0002, S0003, S0004, S0007, S0008, S0009, S0014,		PDC515,		
PDC517, Intervention. PDC518, PDC519, PDC520, PDC521, PDC522, PDC522, PDC523, PDC524, PDC525, PDC526, PDC527, PDC528, PDC530, PDC531, PDC531, PDC533, PDC533, PDC534, PDC535, PDC535, PDC535, PDC536, PDC537, PDC538, PDC538, PDC538, PDC538, PDC538, PDC539, PDC544, PDC541, PDC542, PDC544, PDC545, S0007, S0008, S0009, S0014, S0007, S0008, S0009, S0014, S0007, S0008, S0009, S0014, PDC914, PDC914, PDC544, PDC544, PDC545, PDC540,		PDC516		
PDC518,         PDC520,         PDC522,         PDC522,         PDC523,         PDC524,         PDC525,         PDC526,         PDC527,         PDC528,         PDC529,         PDC531,         PDC533,         PDC534,         PDC535,         PDC534,         PDC535,         PDC536,         PDC537,         PDC538,         PDC538,         PDC534,         PDC536,         PDC537,         PDC538,         PDC536,         PDC537,         PDC538,         PDC540,         PDC541,         PDC542,         PDC543,         PDC544,         PDC545,         PDC544,         PDC544,         PDC545,         PDC546,         PDC552,         SO001, SO002,         SO003, SO004,         SO003, SO004,			intervention.	
PDCS19,         PDCS21,         PDCS22,         PDCS23,         PDCS24,         PDCS25,         PDCS24,         PDC525,         PDC526,         PDC527,         PDC528,         PDC529,         PDC530,         PDC531,         PDC533,         PDC533,         PDC533,         PDC534,         PDC535,         PDC535,         PDC536,         PDC537,         PDC538,         PDC533,         PDC534,         PDC535,         PDC540,         PDC541,         PDC542,         PDC544,         PDC544,         PDC544,         PDC544,         PDC544,         PDC544,         PDC544,         PDC544,         PDC544,         PDC550,         PDC551,         PDC552,         S0001, S0002,         S0003, S0004,         S0007, S008,				
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SO009, SO014,				
SO017, SO018,		SO017, SO018,		

			SO019, SO020, SO021, SO029, SO030, SO031, SO032, SO033, SO034, SO035, SO036, SO037, SO038, SO069, SO086, SO100, SN001, SN002, SN003, SN004, SN005, SN006, SN007, SN008, 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 6 <sup>th</sup> Feb. 2019	Tyshak-Mini PTV Catheter (Valvuloplasty Catheter) PDC400, PDC401, PDC402, PDC403, PDC403, PDC404, PDC405, PDC405, PDC406, PDC406, PDC407, PDC408, PDC409, SO095, SO097, SO098, SO101, SO102, SO103, SO104 Class D Self life 5 Years Rs.50,000/-	The NuMEDTysh ak 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	Co. I the Hand	1	mularia / dua da	
	Co.,Ltd Head	1 covered Stent	pyloric/duode	
Road, Gulberg		(Both Bare-type)	num luminal	
IV, Lahore	ro,Wolgot-myeon,	Class C	patency caused	
	Gimpo-si, Gyeonggi-	Codes:	by intrinsic	
ELI 00087	do, 10022, Korea	PS1806B,	and/or	
	(Republic Of)	PS1808B,	extrinsic	
<b>Evaluator:</b>		PS1810B,	benign	
Ms. Unum Zia	a FSC UK MHRA	PS1812B,	stricture.	
Shamsi	issued on 07.02.2019	PS1814B,		
		PS1815B,		
		PS1816B,		
		PS2006B,		
		PS2008B,		
		PS2010B,		
		PS2012B,		
		PS2014B,		
		PS2015B,		
		PS2016B,		
		PS2206B,		
		PS2208B,		
		PS2210B,		
		PS2210D, PS2212B,		
		PS2212B, PS2214B,		
		PS2214D, PS2215B,		
		PS2216B,		
		PS2406B,		
		PS2408B,		
		PS2410B,		
		PS2412B,		
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		PS2416B,		
		PS2606B,		
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		PS2610B,		
		PS2612B,		
		PS2614B,		
		PS2615B,		
		PS2616B,		
		PS2806B,		
		PS2808B,		
		PS2810B,		
		PS2812B,		
		PS2814B,		
		PS2815B,		
		PS2816B,		
		PST1806B,		
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			PST1806B-12,		
			PST1808B-12,		
			PST1810B- 12, PST1812B-12,		
			PST1812D-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:		
007	1		Rs. 50,000/-	T ( 1 1 C	A 1
237	-do-	Manufacturer:	Niti-S Biliary	Intended for	Approved.
	Evolutor	Taewoong Medical Co.,Ltd Head	Uncovered Stent (S-type)	maintaining biliary luminal	
	<b>Evaluator:</b> Ms. Unum Zia	Office14,Gojeong-	Class C	patency in	
	Shamsi	ro,Wolgot-myeon,	Codes:	malignant	
	~11411101	Gimpo-si, Gyeonggi-	T0604, T0605,	strictures.	
		do, 10022, Korea	T0606, T0607,		
		(Republic Of)	T0608, T0609,		
			T0610, T0612,		
		FSC UK MHRA	T0804, T0805,		
		issued on 07.02.2019	Т0806, Т0807,		
			T0808, T0809,		
			T0810, T0812,		
			T1004, T1005,		
			T1006, T1007,		
			T1008, T1009,		
1			m1010 m1010		
			T1010, T1012 B0604, B0605,		

B0606, B0607, B0608, B0609, B0610, B0612, B0804, B0805, B0806, B0807, B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009, B1010, B1012	
B0610, B0612, B0804, B0805, B0806, B0807, B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009,	
B0804, B0805, B0806, B0807, B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009,	
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B0806, B0807, B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009,	
B0808, B0809, B0810, B0812, B1004, B1005, B1006, B1007, B1008, B1009,	
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BM1004,	
BM1005,	
BM1006,	
BM1000, BM1007,	
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BM1008,	
BM1009,	
BM1010,	
BM1012.	
Shelf life: 3 years	
Fee submitted:	
Rs. 50,000/-	
238-do-Manufacturer:Niti-S EsophagealIntended forApproved	
Taewoong Medical Uncovered Stent maintaining	•
Ms. Unum Zia Office14,Gojeong- Class C luminal	
Shamsi ro,Wolgot-myeon, Codes: patency in	
Gimpo-si, Gyeonggi- E1006, E1008, malignant	
do, 10022, Korea E1010, E1012, strictures.	
(Republic Of) E1014, E1015,	
E1206, E1208,	
FSC UK MHRA E1210, E1212,	
issued on 07.02.2019 E1214, E1215,	
E1214, E1215, E1406, E1408,	
E1410, E1412,	

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	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/- Niti-S Esophageal Covered Stent [Full Covered- Type] Class C Codes: ES1006F, ES1008F, ES1010F, ES1012F, ES1014F, ES1015F, ES1206F, ES1208F, ES1206F, ES1207, ES1212F, ES1212F, ES1214F, ES1412F, ES1414F,	Intended for the use in malignant and /or benign stricture and tracheoesopha geal fistula.	Approved.
			ES1410F, ES1412F, ES1414F,		

ES1808F,
ES1810F,
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			PDT2015-22,		
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			PDT2210-22,		
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			PDT2214-22,		
			PDT2215-22,		
			PDT2406-22,		
			PDT2408-22,		
			PDT2410-22,		
			PDT2412-22,		
			PDT2412-22,		
			PDT2414-22, PDT2415-22.		
			FD12415-22.		
			Shelf life: 3 years		
			Fee submitted:		
			50,000/-		
241	-do-	Manufacturer:	Niti-S Enteral	Intended for	Approved.
241	-40-		Colonic Covered		Approveu.
	E	Taewoong Medical Co.,Ltd Head	Stent (Both Bare-	maintaining colon luminal	
	Evaluator:	CoLla Head	Stent (Doth Dare-		
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	Ms. Unum Zia	Office14,Gojeong-	type)	patency in	
	Ms. Unum Zia Shamsi	Office14,Gojeong- ro,Wolgot-myeon,	type) Class C	patency in colon stricture	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi-	type) Class C Codes:	patency in colon stricture caused by	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea	type) Class C Codes: CS1806B,	patency in colon stricture caused by intrinsic	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi-	type) Class C Codes: CS1806B, CS1808B,	patency in colon stricture caused by intrinsic and/or	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of)	type) Class C Codes: CS1806B, CS1808B, CS1810B,	patency in colon stricture caused by intrinsic and/or extrinsic	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of)	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1814B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1814B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1810B, CS1812B, CS1814B, CS1815B, CS1816B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2008B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2006B, CS2008B, CS2010B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2008B, CS2010B, CS2012B, CS2014B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2006B, CS2010B, CS2012B, CS2014B, CS2015B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2006B, CS2006B, CS2010B, CS2012B, CS2014B, CS2015B, CS2016B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2006B, CS2008B, CS2010B, CS2012B, CS2014B, CS2015B, CS2016B, CS2206B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1815B, CS1816B, CS2006B, CS2006B, CS2010B, CS2012B, CS2012B, CS2014B, CS2015B, CS2016B, CS2206B, CS2206B, CS2208B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1814B, CS1815B, CS1816B, CS2006B, CS2006B, CS2008B, CS2012B, CS2012B, CS2012B, CS2015B, CS2016B, CS2206B, CS2206B, CS2208B, CS2210B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	
		Office14,Gojeong- ro,Wolgot-myeon, Gimpo-si, Gyeonggi- do, 10022, Korea (Republic Of) FSC UK MHRA	type) Class C Codes: CS1806B, CS1808B, CS1810B, CS1812B, CS1812B, CS1815B, CS1816B, CS2006B, CS2006B, CS2010B, CS2012B, CS2012B, CS2014B, CS2015B, CS2016B, CS2206B, CS2206B, CS2208B,	patency in colon stricture caused by intrinsic and/or extrinsic malignant and/or benign	

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			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,		
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			CST1810B,		
			CST1812B,		
			CST1814B,		
			CST1815B,		
			CST2006B,		
			CST2008B,		
			CST2010B,		
			CST2012B,		
			CST2014B,		
			CST2014D, CST2015B.		
			Shelf life: 3 years		
			Fee submitted:		
			Rs.		
			50,000/-		
242	-do-	Manufacturer:	Niti-S Biliary	Intended for	Approved.
		Taewoong Medical	Covered Stent	maintaining	
	<b>Evaluator:</b>	Co.,Ltd Head	(Full Covered-	biliary luminal	
	Ms. Unum Zia	Office14,Gojeong-	Туре	patency in	
	Shamsi	ro,Wolgot-myeon,	Class C	malignant	
		Gimpo-si, Gyeonggi-	Codes:	stricture	
		do, 10022, Korea	TS0604F,		
		(Republic Of)	TS0605F,TS0606		
			F, TS0607F,		
		FSC UK MHRA	TS0608F,TS0609		
		issued on 07.02.2019	F, TS0610F,		
			TS0612F,		
			TS0804F,		
			. /		

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	TS0805F,	
	TS0806F,TS080	7
	F, TS0808F,	
	TS0809F,TS081	n
	F, TS0812F,	
	TS1004F,TS100	5
	F, TS1006F,	
	TS1007F,	
	TS1008F,	
	TS1009F,	
	TS1010F,TS101	2
	F, BS0603F,	
	BS0604F,	
	BS0605F,	
	BS0606F,	
	BS0607F,	
	BS0608F,	
	BS0609F,	
	BS0610F,	
	BS0612F,	
	BS0803F,	
	BS0804F,	
	BS0805F,	
	BS0806F,	
	BS0807F,	
	BS0808F,	
	BS0809F,	
	BS0810F,	
	BS0812F,	
	BS1003F,	
	BS1004F,	
	BSI005F,	
	BS1006F,	
	BS1000F,	
	BS1008F,	
	BS1009F,	
	BS1010F,	
	BS1012F,	
	BSM0603F,	
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	BSM0605F,	
	BSM0606F,	
	BSM0607F,	
	BSM0608F,	
	BSM0609F,	
	BSM0600F, BSM0610F,	
	BSM0612F,	
	BSM0803F,	
	BSM0804F,	
	BSM0805F,	
	BSM0806F,	
	BSM0807F,	
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BSM0808F, BSM0809F, BSM0810F, BSM0812F, BSM1003F, BSM1004F, BSM1004F, BSM1005F, BSM1006F, BSM1007F, BSM1008F,	
BSM1009F,       BSM1010F,         BSM1010F,       BSM1012F         BSM1012F       Shelf life: 3 years         Fee submitted:       Rs. 50,000/-         Rs. 50,000/-       Intended for Approved.	
Evaluator:Taewoong Medical Co.,Ltd HeadColonicmaintainingMs. Unum ZiaOffice14,Gojeong- ro,Wolgot-myeon, theSameOffice14,Gojeong- ro,Wolgot-myeon, do, 10022, KoreaColonicmaintaining colon luminal patency in colon stricture caused byProduct by the same(Republic Of)Codes: CT1806, CT1808, santeadyintrinsic extrinsicMas already been registered in the name of M/s AllianceFSC UK MHRA issued on 07.02.2019Codes: CT2010, CT2012 Shelf life: 3 years Fee submitted: Rs. 50,000/-maintaining colon luminal patency in colon stricture caused by and/or extrinsic	
244M/s. A.HManufacturer:Shunmei®BallooIntended to beRejected asDistributors,M/s.Shunmein Inflation Deviceused in PTCAsame productHouse No. CB-Medical Co., Ltd,Class Boperation, thesame manufa708, Lane No.R401 of building B,Codes:balloonhas already b5, 1st Floor,No.8Jinglong 1st617101dilatationregistered inPeshawarRoad,Baolong617102catheter isname of M/sRoad,Industrial Zone, Long617103pressurized inAlliance MedRawalpindi.gang District, 518116617108order toLahore.ELI-00225Shenzhen,617110expansion ofLahore.Ms. Unum Ziaissued on 20-04-2017617112or thestent.ShamsiFSC U.K MHRA617112or thestent.KamsiFee submitted:stent.stent.stent.	t by the acturer been the s
245-do-Legal Manufacturer:Shunmei (PTFE Coated Guide Wire is applicable asPTFE coated same product same manufacturer	t by the acturer
<b>Evaluator:</b> Medical Co., Ltd, an invasive has already b	
Ms. Hira R401 of building B, Codes as per FSC medical registered in	the

	Bhutto	No.8 Jinglong 1 <sup>st</sup> Road, Baolong Industrial Zone , LongGang District, 518116 Shenzhen, Guangdong, China. Manufacturing Location: M/s. Huizhou Branch of Shunmei Medical Co., Ltd., Vifa 3 <sup>rd</sup> 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.	Alliance Medical, Lahore.
246	-do- <b>Evaluator:</b> Ms. Hira Bhutto	Legal Manufacturer: M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1 <sup>st</sup> Road, Baolong Industrial Zone , LongGang District, 518116 Shenzhen, Guangdong, China. Manufacturing Location: M/s. Huizhou Branch of Shunmei Medical Co., Ltd., Vifa 3 <sup>rd</sup> 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.	<b>Rejected</b> 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, 2 <sup>nd</sup> Floor,12 <sup>th</sup> 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) <u>Evaluator:</u> 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 <u>Evaluator</u> : 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 <u>Evaluator</u> : 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	<b>Deferred</b> 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				
	<u>Evaluator</u> : Ms. Hira				
	Bhutto				
251			Draina ga Tuha	tube.	A newsrad autiest
251	Brothrs	Legal Manufacturer:	Drainage Tube (Drainage tube)	Disposable	Approved subject
	Suite, 7B,	Legai manulacturer.	(Dramage lube)	-	to foreign
	2 <sup>nd</sup> Floor, Abrar	M/s Jiangsu Weikang	Codes:	Drainage tube is akind of	inspection of manufacturer or
	Business	Jiejing Medical	Coues.	medical device	
	Center, 25-	Appaatus Co., Ltd 18	Reference: Size	which is used	provision of CE marked documents
	Mian Wahat	# Wenzhou Rd.	02044201: F24	to drain the	and provision of
	Road	Economic	02044201: F24 02044202: F26	urine from the	stability data
	Lahore	Development District	02044202: F28	body .	supporting shelf life
	Lanoic	Shuyange, (223600	02044203. F28 02044204: F30	Drainage tube	of product.
	ELI- 00133	Jiangsu,) republic of	02044204. F30 02044205: F32	also known as	The Board also
	ELI- 00155	China	02044205. 152	a chest tube or	authorized the
	Evaluator:	Ciiiia	Class B	thoracic	Secretary MDB to
	Ms. Hira			catheter is	
	Bhutto	FSC China	Shelf Life 05	asterile tube	0
	Diracto	Valid till	years	that is inserted	panel of experts
		16 <sup>th</sup> September ,2020	Jearo	into the pleural	approves the
		10 000000000000000000000000000000000000	Rs.25,000/-	space. The	manufacturing
			10.20,0007	patient may	plant.
				require a chest	P <sup>rante</sup>
				drainage	
				system any	
				time the	
				negative	
				pressure in the	
				pleural cavity	
				is disrupted,	
				resulting in	
				respiratory	
				distress.	
252	-do-		SUCKERS		Approved subject
		Legal Manufacturer:		provide blood	to foreign
	Evaluator:		Suckers	suction to	inspection of
	Ms. Hira	M/s Changzhou		ensure a clear	manufacturer or
	Bhutto	Kangxin Medical	Size: L-1, L-2,S-	and dry	provision of CE
		Insturments Co., Ltd	1,S-2	surgical field.	marked documents
		Qiuzhuang, KLuoxi		Suckers are	and provision of
		town Xinbei District,	Class B	used for	Stability data
		Changzhou, Jiangsu,		attracting	supporting shelf life
		China	Shelf Life 03	blood from the	of product and
			years	operating area	
				in cardiac	The Board also
		FSC China		operation to	authorized the
		Valid date 19.03,2020		ensure a clear	Secretary MDB to
				vision	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 <u>Evaluator</u> : 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- <b>Evaluator:</b> 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- <u>Evaluator:</u> 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 24 <sup>th</sup> 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) <u><b>Evaluator:</b></u> 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- <b>Evaluator:</b> 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, 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	provision of EPSPand Stability data supporting shelf life of product.

258	-do- Evaluator: Ms. Hira Bhutto	Legal Manufacturer: SetpaTibbi Gerecler ITH.IHR.SAN.VE.TI C.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance)	Round B.1/2 75cm sterile surgical suture Rs.50,000/- Rs.50,000/- 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/-	suitable for use if applications like general wound closures, ophthalmic surgery, orthopedics, gynecology (episiotomy repair) and gastrointestinal tract surgery. It is not intended for use in cardiovascular of neurological surgery and thus should not be used in those procedures. 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	
259	M/s. Biocare Enterprises, Plot No. 64/2,	Legal Manufacturer:M/s.MeizhouCornleyHi-TechCo.,	Electrolyte Analyser	Electrolyte Analyser	<b>Deferred</b> for provision of Stability data

	Street No. 17, FECHS (Npf) 09, PWD Road, Islamabad. ELI-00220 <u>Evaluator</u> : 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, 1 <sup>st</sup> Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155 <b>Evaluator:</b> 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:3 <sup>rd</sup> July, 2020	NIGALE PLASMA/PLAS MA 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.	and provision of Original notarized ISO 13485 and full
261	-do- <b>Evaluator:</b> 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:12 <sup>th</sup> 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)	<b>Deferred</b> 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: 12 <sup>th</sup> 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) <u>Evaluator</u> : Ms. Hira Bhutto	Legal Manufacturer: VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. FSC – Neherlands Valid till 31 <sup>st</sup> 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.	<b>Approved</b> subject to provision of Stability data.
264	-do- <b>Evaluator:</b> Ms. Hira Bhutto	Legal Manufacturer: M/s VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam- the Neherlands. FSC – Neherlands Valid till 31 <sup>st</sup>	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	Evaluator: Ms. Hira Bhutto	Legal Manufacturer: VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. FSC – Neherlands Valid till 31 <sup>st</sup> 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 hyluronate, sodium hydrogenphos phate, sodium dihydrogen phosphate and water for injection	Approved.
266	-do- <u>Evaluator</u> : Ms. Hira Bhutto	Legal Manufacturer: M/s VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam- the Neherlands. FSC – Neherlands	Acriva UD 613 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 31 <sup>st</sup>	MFM 611		
		January,2021			
		5411441 y ,202 1	Class-C		
			Shelf Life:5 years		
			Rs.50,000/-		
267	M/s.	Manufacturer:	BROCHE	Sterile drapes	Approved subject
	Medicamp	M/s. Nurteks Tekstil	(Sterile disposable	are used	to foreign
	International,	ve Medikal Sanayi Dis	surgical drape and	during surgery	inspection of
	Office No. 1,	Tic. A.S., Kosklu	drape sets)	for stopping	manufacturer and
	First Floor,	Cesme, Mah. Yeni		the	provision of
	Raja Naseer	bagdat Cad. No. 124	Product Codes:	contamination	Stability studies,
	Plaza, Mohalla	Gebze / Kocaeli-	960990900076	as preventing bacteria	validation protocol and differential fee.
	Raja Yousaf, New Abadi	Turkey.	8698898292076, 8698898292021	transfer	and differential fee.
	Morgah,	FSC Turkey	8698898292021	coming from	The Board also
	Rawalpindi.	Expiry on 5 <sup>th</sup>	8698898292069	sick's skin and	authorized the
	I	December, 2020	8698898291222	incision areas.	Secretary MDB to
	ELI-00200		8698898291918,		issue registration of
			8698898291895		the product, if the
			8698898291970		panel of experts
	Evaluator:		8698898292137,		approves the
	Ms. Hira		Class D		manufacturing
	Bhutto		Class B Shelf Life : 05		plant.
			years		
			Rs.25,000/-		
268	M/s. Ameer	Legal Manufacturer:	Opto-Pharm P2	As a cleaning,	Approved subject
	Sons	OPTO-PHARMA	Penta-Plex Multi-	biofilm	to foreign
	305-A Upper	PTE LTD	Purpose solution	(protein and	inspection of
	Mall,	13 Tuas Ave 12	(No Rub)	lipid)	manufacturer.
	Lahore	Singapore	1 00 00 50	removing,	
	(ELI-00058)	ESC Singanana	MPS 0350 MPS 0120	disinfecting,	The Board also
		FSC – Singapore Issuance 4 <sup>th</sup>	MPS 0120 MPS 0010	storing, rinsing,	authorized the Secretary MDB to
	Evaluator:	January,2019	1111 3 0010	wetting,	issue registration of
	<u>Evaluator</u> . Shahid	5 airour 5,2017	Class C	lubricating,	the product, if the
	Muhammad			and comfort	panel of experts
	Iqbal			enhancing	approve the
			Shelf Life (	solution for all	manufacturing
			MULTI DOSE)	soft and hard	plant.
			48 months	contact lenses	
			Chalft : f- (TINIT	include	
			Shelf Life (UNI- DOSE, 10ml) 36	disposable, colored and	
			months	silicone	
				hydrogel	
			Rs.50,000/-	lenses.	
269	M/s. Mezan		ACTOSED	Aldehyde	Approved subject
	International	Legal Manufacturer:	FORTE	based ready to	to foreign
	59 BR II,	M/s ACTO Pharma	READY-5L	use	inspection of
	Opp.DCO,	HIJYEN SANAYI		disinfectant for	manufacturer and

	House Haji Meherban Road, Jhelum ELI-00096. <u>Evaluator</u> : 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) <u><b>Evaluator:</b></u> 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 contraindicate d.	Approved.
271	M/s Briogene (Pvt) Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) <b>Evaluator:</b> 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	<b>Approved</b> subject to provision of differential fee and Form 7-A.
272	-do- <b>Evaluator:</b> 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	<b>Approved</b> subject to provision of differential fee and Form 7-A.

		on 21 02 2010)	Months	acids from	<u> </u>
		on 21-02-2018)	Months Fee submitted: Rs	biological	
			5,000/-	specimens for	
			5,0007 -	in vitro	
				diagnostic	
				purposes	
273	-do-	Manufacturer:	QIAmp® DSP	Uses silica-	Approved subject
210	üõ	QIAGEN GmbH,	Virus Kit	membrane	to provision of
		QIAGEN Str. 1, 40724	Class B	technology for	differential fee and
	<b>Evaluator:</b>	Hilden Germany	Code: 60704	isolation and	Form 7-A.
	Ms. Unum Zia	(FSC Germany issued	50 tests	purification of	
	Shamsi	on 21-02-2018)	Shelf life: 24	viral nucleic	
			Months	acids from	
				human plasma	
			Fee submitted: Rs	or serum	
			5,000/-	samples for in	
				vitro	
				diagnostic	
				purposes	
274	-do-	Manufacturer:	QIAsymphony®	Uses magnetic	Approved subject
		QIAGEN GmbH,	DSP	particle-	to provision of
	<b>T 1</b>	QIAGEN Str. 1, 40724	Virus/Pathogen	technology for	differential fee and
	Evaluator:	Hilden Germany	Kit Class B	automated	Form 7-A.
	Ms. Unum Zia	(TCO O	Class B Code:	isolation and	
	Shamsi	(FSC Germany issued	QIAsymphony®	purification of viral and	
		on 21-02-2018)	DSP	bacterial	
			Virus/Pathogen	nucleic acids	
			Mini Kit (192)-	from biological	
			937036	specimens for	
			QIAsymphony®	in vitro	
			DSP	diagnostic	
			Virus/Pathogen	purposes	
			Midi Kit (96)-		
			937055		
			Shelf Life: 18		
			Months		
			Fee submitted: Rs		
			5,000/-		
275		Legal Manufacturer:	Golden + Silicon	Foley Catheter	Approved subject
	Impex,	Haiyan Kangyuan	Foley Catheter	(Urinary	to foreign
	SH.40, Namco	Medical Instrument		Catheter)	inspection of
	Centre,	Co., Ltd	Class B		manufacturer and
	Cambell Street,	Songpodong Rd.,	Shalf I for 5		provision of valid
	Karachi.	Shengdang Town,	Shelf Life: 5 Years		Free Sale Certificate.
	(ELI-00170)	Haiyan Zhejiang Province, China.	Sizes:		Certificate.
		r iovince, cillia.	(6,8,10,12,14,16,1		The Board also
	Evaluator:	(FSC China Valid till	8,20,22,24,26,28)		authorized the
	Hafiz	08-07-2019)	Fr		Secretary MDB to
	Muhammad				issue registration of
	Asif Iqbal		Rs.25,000/-		the product, if the
			,000.	1	product, if the

			panel of experts approve the manufacturing plant.
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#### Item No.XXVI.RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

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:-

<b>S</b> .	Name and	Manufacture Details	Name of Medical	Brief	Decision
Ν	Addresses of		Device with	Description	
0	Establishment		sizes/Class/Shel		
			f Life		
1.	M/s K.S.	Legal Manufacturer:	Glylon	For Skin	Approved
	Agencies,		(Nylon	Closure in	subject to
	Suit# 210, 2 <sup>nd</sup>	Huaiyin Medical	Monofilament	general	foreign
	Floor, Business	Instruments Co., Ltd,	Polyamide)	surgery, plastic	inspection of
	Arcade, Main	No.8 West Mingyuan		surgery,	manufacturer
	University Road	Road, Huain City	Synthetic non-	gastrointestinal	and provision
	Karachi.	China.	absorbable	surgery,	of Notarized
			surgical suture	gynecology,	ISO, FQA,
	(ELI-00382)	(FSC China Valid Till	-	obstetrics &	Mnaufacturing
		17-01-2021)	Class C	orthopedics.	and QC
	Evaluator:				documents,
	Ms. Hira Bhutto		Shelf Life: 5		Stability data,
			years		EPSP and
					original
			Sizes as per FSC		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-	Legal Manufacturer:	Glylene	For use in	Approved
۷.	-40-			general soft	subject to
	Evaluator:	Huaiyin Medical	Monofilament	tissue	foreign
	Ms. Hira Bhutto	Instruments Co., Ltd,	Polypropylene	approximation	inspection of
	1410, 1111a Diluito	No.8 West Mingyuan	non absorbable	and / or	manufacturer
		Road, Huain City	surgical suture	ligation,	and provision
L		Koau, muain City	surgical suture	nganon,	

		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- Evaluator: 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 approximation s and or ligation, especially in general surgery, skin closures, Gastrointestina l 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,EP SP 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-	Legal Manufacturer:	Catgut Chromic	Suture, absorbable,	Approved subject to
	Evaluator:	Huaiyin Medical	Catgut Chromic	non-synthetic,	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- <b>Evaluator:</b> 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- Evaluator: 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- <b>Evaluator:</b> 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

plant.						MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
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#### Item No. XXVII.<u>REGISTRATION OFMEDICAL DEVICES FOR LOCAL</u> <u>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	Name of Medical Device/	Brief Description	Remarks
	Address of Firm	Shelf Life/ Class of MD	_	
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><b>Evaluator:</b></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	<b>Approved</b> 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 <u>Evaluator</u> : 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	Name of Medical Device	Brief Description/ Shelf	Remarks
	Address of Firm		Life/ Class of MD	
1.	M/s Asian Fibre, Plot No. 41-42, Sector 25, K.I.A, Karachi <u>Evaluator:</u> 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)	Used for construction of common orthopedic casts, plastic surgery and for the external fixation of fractures and sprains	Approved subject to GMP inspction.
		Fee submitted: Rs. 5,000/-		
2.	-do-	Softban Under-Cast Padding	Used as a pad for orthopedic casting tape	Approved subject to

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

### 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  $14^{th}$  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 <sup>™</sup> Polypropylene Mesh Codes: PMM3 (CE-marked) PMS1 (CE-marked) PMS1 (CE-marked) PMS1 (CE-marked) PMSX1(CE-marked) PML1(CE-marked) PML3 (non-CE marked) PMH (non-CE marked) PMII (non-CE marked) PMLK (non-CE marked) PMXL (non-CE marked) PMXS (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-	Legal Manufacturer:	PROLENE ™Polypropylene	A monofilament,	<b>Deferred</b> forclarification
<u>Evaluator:</u> Ms. Unum Zia Shamsi	Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA, 00754.	Suture (Polypropylene, Monofilament, Sterile, Synthetic, Non- Absorbable Surgical	synthetic, non- absorbable, sterile surgical suture composed of	of codes of medical device.

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

W8525         W8549         W8556         W8557         W8558         W8571         W8597	
W8556           W8557           W8558           W8571	
W8557           W8558           W8571	
W8558 W8571	
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	
W8430G W8307G	
W850/G W8731G	
W8761G	
<u>8686H</u>	
Shelf Life: 60 Months	
Fee submitted: Rs.	
50,000/-	
-do- Legal Ethicon® Monocryl <sup>TM</sup> Sterile, Deferred	or
Manufacturer:Plus AntibacterialSynthetic,Definition	
<b>Evaluator:</b> Johnson and (Poliglecaprone 25) absorbable codes of m	edical
Ms. Unum Zia ShamsiJohnsonSuturemonofilamentdevice.	

International c/o		suture
European Logistics	Class D	prepared from
Centre, Leonardo		a co-polymer
*		1 0
Da Vincilaan 15, B	Codes:	of glycolide
E-1831 Diegem,	MCP3205G	and e-
Belgium	MCP3650G	caprolactone.
	MCP500H	Intended for
Manufacturing Site:		use in general
Johnson and	Shelf Life: 5 years	soft tissue
Johnson Medical		approximation
Limited, Simpson	Fee submitted: Rs.	and/or ligation
Parkway, Kirkton	50,000/-	wherein an
Campus, Livingston,	, ,	absorbable
Scotland, EH54		material is
7AT, United		indicated
Kingdom		mailaila
12111500111		
(FSC Belgium issued		
on 3-5-2019)		
011 3-3-2019)		

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 15<sup>TH</sup> MEDICAL DEVICE BOARD MEETING HELD ON 30<sup>TH</sup> DECEMBER, 2019

### Agenda Item NO:1

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

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

				mitral valve leaflets.	
3	-do-	<ol> <li>Legal Manufacturer: ABBOTT VASCULAR</li> <li>3200 Lakeside drive,</li> <li>Santa Clara , CA 95054</li> <li>Manufacturing Site:</li> <li>ABBOTT VASCULAR</li> <li>3885 BOHANNON Drive</li> <li>Menlo Park, CA USA 94025</li> </ol>	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	Approved only with code SGC0301
				Clip Implant for proper positioning and placement on the mitral valve leaflets.	
4	-do-	<ol> <li>Legal Manufacturer: ABBOTT VASCULAR 3200 Lakeside drive, Santa Clara , CA 95054</li> <li>Manufacturing Site: ABBOTT VASCULAR 3885 BOHANNON Drive Menlo Park, CA USA 94025</li> </ol>	MITRACLIP ACCESSORY- LIFT Code: LFT01ST Class: A Shelf Life: N/A Eag: 5000/	MitraClip Reusable Accessories are intended to provide a stable platform to support the MitraClip Delivery System	Approved
5	-do-	<ol> <li>Legal Manufacturer: ABBOTT VASCULAR</li> <li>3200 Lakeside drive,</li> <li>Santa Clara , CA 95054</li> <li>Manufacturing Site:</li> <li>ABBOTT VASCULAR</li> <li>3885 BOHANNON Drive</li> <li>Menlo Park, CA USA 94025</li> </ol>	Fee: 5000/- MITRACLIP ACCESSORY- SUPPORT PLATE Code: PLT01ST Class: A Shelf Life: N/A Fee: 5000/-	Delivery System. MitraClip Reusable Accessories are intended to provide a stable platform to support the MitraClip Delivery System.	Approved
6	-do-	<ol> <li>Legal Manufacturer: ABBOTT VASCULAR</li> <li>3200 Lakeside drive,</li> <li>Santa Clara, CA 95054</li> <li>Manufacturing Site:</li> </ol>	MITRACLIP ACCESSORY- STABILIZER Code: SZR01ST	MitraClip Reusable Accessories are intended to provide a stable	Approved

### 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 26<sup>th</sup> 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 31<sup>st</sup> 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 31<sup>st</sup> 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.