

**DECISIONS OF 76TH MEETING OF MEDICAL DEVICE BOARD
HELD ON 26-12-2024**

**REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C & D)
FOR LOCAL MAUFACTURE**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision of MDB
1.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [464-7L]	NEO-SAPTI GRASS Chlorhexidine Tulle Class D Shelf Life: 5 Years Fee: 20000 Fee Slip: 643918697137	Approved. The applicant will clarify for application submitted “for export purpose only” instead of routine registration application.
2.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-000) [610-6L]	Medpro By-Pass Drape Pack Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 3511949383	Deferred for clarification regarding intended use of the product with respect of By pass surgery & the risk classification as per the Medical Device Rule 2017.
3.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-000) [610-6L]	Medpro Cardiovascular Drape Pack Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 01997387	Deferred for clarification regarding intended use of the product with respect of Cardiovascular procedure & the risk classification as per the Medical Device Rule 2017.
4.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-000) [610-6L]	Medpro Advance Delivery Drape Pack Class A Shelf Life: 3 Years Fee: Fee Not attached	Deferred for clarification regarding intended use of the product with respect of Delivery procedure & the risk classification as per the Medical Device Rule 2017. The firm shall also submit the evidence of submission of prescribed fee.
5.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-000) [610-6L]	Medpro Liver Transplant Drape Pack Class A Shelf Life: 3 Years Fee: Fee Not attached	Deferred for clarification regarding intended use of the product with respect of Delivery procedure & the risk classification as per the Medical Device Rule 2017. The firm shall also submit the evidence of submission of prescribed fee.
6.	Hzins International,	HI-JECT Disposable Infusion Set	Approved.

	Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [564-L] Dec-24	Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 531299405481	
7.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [565-L] Dec-24	HI-JECT Y-PORT Disposable Infusion Set Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 29437939185	Approved.
8.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [566-L] Dec-24	HI-JECT Disposable Infusion Set with Burette Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 57088151598	Approved.
9.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [567-L] Dec-24	HI-JECT Auto Disable Syringe Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 61464744550 Sizes: 1, 2, 3,5mL	Approved.
10.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [568-L] Dec-24	HI-JECT Blood Transfusion Set Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 607355116906	Approved.
11.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [569-L] Dec-24	HI-JECT IV Flow Regulator Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 30064134054	Approved.
12.	Hzins International, Plot No. A/10-Q, SITE Area Hyderabad (ELM-00085) [570-L] Dec-24	HI-JECT 3-Way Stopcock Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 8311005906	Deferred for confirmation of the manufacturing & testing facility for the applied product.

13	DKT Pakistan Private Limited, chak No. 1/JB near Pull Dingro, Sargodha Road, District Faisalabad Lic. No.ELM-0080	Heer Ultra Load (IUCD TCU 380S with Steriload Applicator) Pro-Green Edition Class D Shelf Life: 7 Years Fee: 25000 Fee Slip No. 76273123705	Approved.
14	DKT Pakistan Private Limited, chak No. 1/JB near Pull Dingro, Sargodha Road, District Faisalabad Lic. No.ELM-0080	Heer Slime Line (IUCD TCU 380S) Pro-Green Editio Class D Shelf Life: 7 Years Fee: 25000 Fee Slip No. 8311005906	Approved.
15	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Auto-disable Syringe Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 15261570951 Sizes: 0.1, 0.3, 0.5, 1, 2, 2.5, 3, 5mL	Approved.
16	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Insulin Syringe Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 61902157 Sizes: 0.3, 0.5, 1 mL	Approved.
17	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Syringes Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 62466781546 Sizes: 10, 20. 30, 50, 60mL	Approved. Firm is advised to submit catalogue of the product applied.

18	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable IV Set Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 120377688772	Approved. Firm is advised to submit catalogue of the product applied.
19	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Infusion Set with Precision Filter Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 56921091660	Approved. Firm is advised to submit catalogue of the product applied.
20	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Infusion Set with Y-port Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 70649917	Approved. Firm is advised to submit catalogue of the product applied.
21	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus IV Cannula with Wing and Injection Port Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 7799133227 Sizes :16,18,20,22,24,26G	Approved. Firm is advised to submit catalogue of the product applied.
22	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus IV Cannula without Wing and with Injection Port Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 25909524958 Sizes :16,18,20,22,24,26G	Approved. Firm is advised to submit catalogue of the product applied.
23	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore	Venus IV Cannula with Moveable Wing (With heaprin lock)	Approved the product IV cannula with a movable wing. While the others products IV

	Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 8478302658 Sizes :16,18,20,22,24,26G	Cannula with Heparin Lock & IV Cannula without Heparin Lock are also approved subject to submission the prescribed fee.
24.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus IV Cannula Pen Type Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 484290393828 Sizes :16,18,20,22,24,26G	Approved. Firm is advised to submit catalogue of the product applied.
25.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus IV Cannula Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 019915046229 Sizes :16,18,20,22,24,26G	Approved. The firm shall clarify the type of the cannula.
26.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Scalp Vein Set Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 94756414352 Sizes: 20,22,23,24,25,27G	Approved. Firm is advised to submit catalogue of the product applied.
27.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Hypodermic Needle Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 930456095 Sizes: 16,17,18,21,23,24,26,27G	Approved. Firm is advised to submit catalogue of the product applied.
28.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site:	Venus Tonsil Needle Class B Shelf Life: 5 Years	Approved. Firm is advised to submit catalogue of the product applied.

	6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Fee: 25000 Fee Slip No. 05382276	
29.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Biopsy Needle Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 734281747998	Approved. The firm shall clarify the specify organ or body area wherefrom the biopsy is to be done.
30.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Dental Needle Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1925697401 Sizes: 25, 27, 30G	Approved. Firm is advised to submit catalogue of the product applied.
31.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Fistula Needle Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 40698737 Sizes: 14-17G	Approved. Firm is advised to submit catalogue of the product applied.
32.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Umbilical Cord Clamp Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 58487469 Sizes: NA	Approved. Firm is advised to submit catalogue of the product applied.
33.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Feeding Tube Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 02528186 Sizes: 8-16 Fr	Approved. Firm is advised to submit catalogue of the product applied.

	Lahore (ELM-00084)		
34.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Nasogastric Stomach Tube Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 73980194065 Sizes: 4,5,6,7,8,10,12,14,16,1,20,22,24	Approved. Firm is advised to submit catalogue of the product applied.
35.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable IV Burette Set Class C Shelf Life: 5 Years Fee: 25000 Fee Slip No. 7407610444 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
36.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Endotracheal Tube with cuff Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 120253719884 Sizes:2.5,3,3.5, 4, 4.5, 5,5.5	Approved. Firm is advised to submit catalogue of the product applied.
37.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Nelation Tube Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 975689573677 Sizes:8,10,12,14,16,18,20,22,24,26,28,30, 32	Approved. Firm is advised to submit catalogue of the product applied.
38.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Pressure Monitoring Line Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1216000389 Sizes :30,60,90,120,150,210,300cm	Approved. Firm is advised to submit catalogue of the product applied.
39.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens	Venus Heparin Cap	Approved. Firm is advised to submit catalogue of the product

	Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 3146489464132 Sizes:NA	applied.
40	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Blood Transfusion Set Class C Shelf Life: 5 Years Fee: 25000 Fee Slip No. 54162962947 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
41	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Blood Transfusion Set with Filter Disposable Blood Transfusion Set with Filter Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 64211550 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
42	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Dialysis Set Class C Shelf Life: 5 Years Fee: 25000 Fee Slip No. 565131930 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
43	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Three way Stopper with Tubing Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 40698737 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
44	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site:	Venus Foley Catheter 3 way Class B Shelf Life: 5 Years Fee: 25000	Approved the product Venus Foley Catheter two way While the others product Venus Foley Catheter 3 way also approved subject to submission the

	6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Fee Slip No. 66429852301 Sizes:6-26	prescribed fee.
45	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Silicon Foley Catheter 2 way Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 271686530 Sizes:6-26	Approved the product Venus Silicon Foley Catheter two way While the others product Venus Silicon Foley Catheter 3 way also approved subject to submission the prescribed fee.
46	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Eye pad Bandage BPC Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 943609888 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
47	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Cotton Bandages Cotton Bandage BPC Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 578058110195 Sizes: 6cm x 4m, 8cm x 4m, 10cm x 4m, 15cm x 4m	Approved. Firm is advised to submit catalogue of the product applied.
48	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Absorbent Gauze Roll Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 5467837536 Sizes:1x2.5M	Approved. Firm is advised to submit catalogue of the product applied.
49	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind	Venus Gauze BPC (Non Sterile) Gauze Swabs and Gauze Roll BPC Class A Shelf Life:3 Years Fee: 6000	Approved the product Gauze Swabs While the others products Venus Gauze Roll also approved subject to submission the prescribed fee.

	Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Fee Slip No. 12873465543 Sizes:10x10cm	
50.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Gauze BPC (Sterile) Swabs and Sponges Class B Shelf Life: 3Years Fee: 25000 Fee Slip No. 16639786995 Sizes:10x10cm 8ply	Approved the product Gauze Swabs While the others product Venus Sponges also approved subject to submission the prescribed fee.
51.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Non-Woven Dressing Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3951457326 Sizes:9x10cm, 9x20cm, 9x30cm,9x35cm	Approved. Firm is advised to submit catalogue of the product applied.
52.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Cotton Crepe Bandages Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 410149726 Sizes:3x4.5M, 4x4.5M, 6x4.5M	Approved. Firm is advised to submit catalogue of the product applied.
53.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Elastic Crepe Bandages Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 2168676755 Sizes: (15cm x 4m), (10cm x 4m), (8cm x 4m), (6cm x 4m).	Approved. Firm is advised to submit catalogue of the product applied.
54.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp.	Venus Gauze (Lap Sponges with X-Ray Thread) Class B Shelf Life: 5 Years Fee: 25000	Approved. Firm is advised to submit catalogue of the product applied.

	Sunder Industrial Estate, Lahore	Fee Slip No. 584258248431 Sizes:30x30cm 4 ply, 10x25cm 15ply	
55.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore	Venus Dressing Tape Roll Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 4916961048 Sizes:10cm	Approved. Firm is advised to submit catalogue of the product applied.
56.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore	Venus Alcohol Swab Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 242950762 Sizes:NA	Approved. Firm is advised to submit catalogue of the product applied.
57.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore	Venus Gelatin Swab / Sponges Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 8478302658 Sizes:NA	Approved subject to revised Form with correct risk class & balance fee.
58.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Povidone / Iodine Swab Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 04927384340 SizesNA	Approved. The class of the product will be determined as per risk classification given in rules
59.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road,Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Paraffin Gauze Wax Class C Shelf Life: 3 Years Fee: 25000 Fee Slip No. 9137934860 Sizes:10x10cm	Approved. Firm is advised to submit catalogue of the product applied.
60.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore	Venus Tulle Sterile (Chlorhexidine acetate 0.5%)	Approved with Class-D. The firm shall submit revised Form with correct risk Class.

	Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Class C Shelf Life: 3 Years Fee: 25000 Fee Slip No. 40593648874 Sizes: 10x10cm, 15x20cm	
61.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore Manufacturing Site: 6-KM, Off Manga Raiwind Road, Glamour Stop, Opp. Sunder Industrial Estate, Lahore (ELM-00084)	Venus Disposable Spine Needle Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1101331590 Sizes: 18-27G	Approved in Class-D
62.	Lab Diagnostic Systems (SMC) Pvt Ltd., Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi (ELM-0028)	R-test Dengue IgG/IgM & Chikungunya IgG/IgM Rapid Test Dengue IgG/IgM & Chikungunya IgG/IgM Rapid Test Class: C Shelf-life: 24 months Sizes: 50 pcs / pack Fee Challan No. 653275791516 Rs. 20,000/- and a differential fee of 5000/ Rs Challan #: 814768678	Approved.
63.	M/s Surgi Plast, Plot No.78, Road No.L-4, Industrial Estate, Gadoown Amazai, KP.	Clinic Blood Transfusion Set Blood Transfusion Set Class: B Shelf-life: 05years Sizes: 20-22 G for adults, 16-18 for rapid transfusion in adults, 22-25G for Pediatrics Fee Challan No. 878515152 Rs. 20,000/-	Approved as the firm has the IV Set facility.
64.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) Approved Section: Disposable syringes I.V Sets	UniPen Intravenous Cannula without injection port & without wings (Pen Type) Class: B Shelf Life: 5 Years Fee: Rs. 20,000/- Challan No. 26017586311 Sizes: 14G-26G	Approved
65.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan	Unican Plus Intravenous Cannula with injection port with suturable wings & Injection Stopper (Heparin Cap)	Approved

	(ELM-0002) Approved Section: Disposable syringes I.V Sets	Class: B Shelf Life: 5 Years Fee: Rs. 20,000/-Challan No. 405721739 Sizes: 14G-26G	
66	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) Approved Section: Disposable syringes I.V Sets	Unitriway Intravenous Cannula with integrated three way stop cock Class: B Shelf Life: 5 Years Fee: Rs. 20,000/-Challan No. 3331636215 Sizes: 14G-26G	Approved

**DEFERRED CASE OF M/S KAMION PHARMA, KARACHI DEFERRED IN
66TH MEETING OF MDB**

Sr.No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision of MDB
1.	Kamion Pharma Plot No. G/4-C, SITE, Super Highway, Phase-II, Karachi [ELM-0070] Sections: i.Adhesive Section ii.Plaster/Patches Section iii.Sterile Dressing / Wound Dress Section iv. Gauze/Sponge Section v.Bandage Section vi.Surgical Tape Section	Kamigauze X-Ray Detectable Abdominal Sponges BPC Sponge Class: A Shelf-life: 03 Years Sizes: 5cm x 5cm (4 ply) 7.5cm x 7.5cm (4 ply) 10cm x 10cm (4 ply) 15cm x 15cm (4 ply) 5cm x 5cm (8 ply) 7.5cm x 7.5cm (8 ply) 10cm x 10cm (8 ply) 15cm x 15cm (8 ply) Fee Rs. 5,000/- slip No. 317722748149	Approved.
2.	Kamion Pharma Plot No. G/4-C, SITE, Super Highway, Phase-II, Karachi [ELM-0070] Sections: i.Adhesive Section ii.Plaster/Patches Section iii.Sterile Dressing / Wound Dress Section iv. Gauze/Sponge Section	Kamistat Heamostatic Rapid Clot Heamostatic Gauze Class: C Shelf-life: three year Sizes: 5cm x 5cm 10cm x 10cm 15cm x 15cm 10cm x 100cm Z Fold	Approved.

v.Bandage Section vi.Surgical Tape Section	10cm x 150cm Z Fold 15cm x 100cm Z Fold Fee Rs. 20,000/-	
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REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C & D) FOR IMPORT

Sr. No.	Name & Address of the importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturer	Name of Medical Devices/ Shelf life /Class & codes / sizes (if any)	Decision
1.	M/s Ferozsos Laboratories Limited P.O Ferozsos, Amangarh, Newshehra, Kpk Pakistan. (ELI-00120)	Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. <u>Manufacturing Site:</u> Boston Scientific Limited Ballybrit Business Park Galway Ireland CFS010597 Date of issue 20-01-2025	SYNERGY Sheild Monorail Everolimus -Eluting Platinum Chromium Coronary Stent System (Drug-eluting coronary artery stent, bioabsorbable-polymer-coated) Class-D Shelf life: 24 Months Codes as per FSC:	Approved
2.	M/s Ferozsos Laboratories Limited P.O Ferozsos, Amangarh, Newshehra, Kpk Pakistan. (ELI-00120)	Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. <u>Manufacturing Site:</u> Boston Scientific Neuromodulation Corporation 25155 Rye Canyon Loop Valencia, CA USA 91355 FSC US FDA validity 17-10-2025 (Original)	Vercise Genus (Deep Brain Stimulation System) Class-D Shelf life: 2 years Cat No. Vercise Genus P8 Implantable Pulse Generator kit (DB-1408) Vercise Genus P16 Implantable Pulse Generator kit (DB-1416) Vercise Genus P32 Implantable Pulse Generator kit (DB-1432) Vercise Genus R16 Implantable Pulse Generator kit (DB-1216) Vercise Genus R32 Implantable Pulse Generator kit (DB-1232)	Approved.
3.	M/s Siemens Healthcare (Pvt) Limited, 4th	Legal manufacturer: Siemens Shanghai Medical Equipment Ltd (SSME), 278	Multix Impact-E (Stationary Basic Diagnostic X-ray System, digital)	Approved.

	Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore	Zhou Zhu Road, 201318 China. FSC China validity 18-06-2025 (original)	Class-C Service Life: 10 years Model: 11333999 (DoC) Software version VB20	
4.	M/s Siemens Healthcare (Pvt) Limited, 4th Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore	<u>Legal manufacturer:</u> Siemens Shanghai Medical Equipment Ltd (SSME), 278 Zhou Zhu Road, 201318 China. FSC China validity 18-06-2025 (original)	Somato X.Cite (X-ray Equipment for Computed Tomography) Class-C Service Life: 10 years Model: 11501200 (DoC) Software version VB10	Approved.
5.	Cardiac Care, 848-C, Shadman-1, Lahore. ELI: 00070	<u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany. FSC Germany Issuance 29-03-2019	Lifecath Brovaic (Silicone central venous catheter with subcutaneous cuff for long-term venous access) Class-D Shelf life: 05 years Art. No. 2191	Deferred for the submission of valid FSC, ISO 13485, FQA and DEC.
6.	Cardiac Care, 848-C, Shadman-1, Lahore. ELI: 00070	<u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany. FSC Germany Issuance 29-03-2019	Lifecath Hickman (Silicone central venous catheter with subcutaneous cuff for long-term venous access) Class-D Shelf life: 05 years Art. No. 2193	Deferred for the submission of valid FSC, ISO 13485, FQA and DEC.
7.	Cardiac Care, 848-C, Shadman-1, Lahore. ELI: 00070	<u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany. FSC Germany Issuance 29-03-2019	Lifecath Biflux (Radiopaque Double-lumen Silicone catheter with subcutaneous cuff for long-term venous access) Class-D Shelf life: 05 years Art. No. 2293	Deferred for the submission of valid FSC, ISO 13485, FQA and DEC.

8.	M/s Mezan International, 59BR-II Opp DCO House Haji Meherban Road Bilal Town, Jhelum 49600 ELI:00096	<u>Legal Manufacturer:</u> Zhejiang Soudon Medical Technology Co., Ltd room 302-1, Floor 3, building 4 & Rpoom 505, Floor 5, Building 8, No. 1 Nangonghe Road, Donghu Street, Linping District, Hangzhou City, China. FSC China validity 12-09-2025 (Original)	Soudon Medical (Disposable Sphinctrotome) Class-C Shelf life: 3 years Sizes: SD-07-A20 SD-07-A30 SD-07-B20 SD-07-A25 SD-07-B25 SD-07-B30	Deferred for submission of revised form-7A as the brand name and generic mentioned on submitted Form is Disposable biliary drainage catheter and valid CE certificate.
9.	M/s Global Marketing Services 111 Hali Road, Westridge 1, Rawalpindi. ELI-00109	<u>Legal Manufacturer:</u> Hologic, Inc. 10210 Genetic Center Drive San Diego, CA 92121 USA +1 800 442 9892 customersupport@hologic.com +1 888 484 4747 Certificate of Exportability US FDA validity 28-03-2026 Premarket Approval (PMA) Ref. No. P210029	Aptima CMV Quant Assay (CMV Quantitative NAT Assay Kit) Class-C Shelf life: 24 Months Ref. No. Aptima CMV Quant Assay 100-test kit (PRD-05074) Aptima CMV Quant Target Enhancer Reagent (TER) (PRD-05077) Aptima CMV Quant Calibrator Kit (PRD-05075) Aptima CMV Quant Controls Kit (PRD-05076)	Approved
10.	M/s Global Marketing Services 111 Hali Road, Westridge 1, Rawalpindi. ELI-00109	<u>Legal Manufacturer:</u> Hologic, Inc. 10210 Genetic Center Drive San Diego, CA 92121 USA +1 800 442 9892 customersupport@hologic.com +1 888 484 4747 FSC US FDA validity 28-03-2026	Aptima Combo 2 Assay (Target amplification nucleic acid probe test, IVD qualitative detection kit) Class-C Shelf life: 24 Months Ref. No. 100-test kit (PRD-05576) 250-test kit (PRD-05571)	Approved
11.	Raffay Associates OFFIVCE NO 04,2nd FLOOR AHMED PLAZA	<u>Legal Manufacturer:</u> Sewoon Medical Co., Ltd 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-Si,	Bonastent (Self-Expandable Metallic Duodenal/ Pyloric Covered Stent)	Approved

	RANGE ROAD RAWALPINDI ELI-00021	Chungcheongnaamdo, Korea. FSC Korea issue on 16-08-2023 FSC Belgium issued on 17- 05-2022	Class-C Shelf life: 3 years Codes as per FSC	
12.	Raffay Associates OFFICE NO 04,2nd FLOOR AHMED PLAZA RANGE ROAD RAWALPINDI ELI-00021	<u>Legal Manufacturer:</u> Sewoon Medical Co., Ltd 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-Si, Chungcheongnaamdo, Korea. FSC Korea issue on 16-08-2023 FSC Belgium issued on 17- 05-2022	Bonastent (Self-Expandable Metallic Duodenal/ Pyloric Un-Covered Stent) Class-C Shelf life: 3 years Codes as per FSC	Approved
13.	Raffay Associates OFFICE NO 04,2nd FLOOR AHMED PLAZA RANGE ROAD RAWALPINDI ELI-00021	<u>Legal Manufacturer:</u> Sewoon Medical Co., Ltd 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-Si, Chungcheongnaamdo, Korea. FSC Korea issue on 16-08-2023 FSC Belgium issued on 17- 05-2022	Bonastent (Self-Expandable Metallic Esophageal with Shim Anti reflux valve Covered Stent) Class-C Shelf life: 3 years Codes as per FSC	Approved
14.	M/s Intek Corporation, Office # 501-502, Kohistan Towers Mehfooz Road, Saddar Rawalpindi ELI: 00794	<u>Legal Manufacturer:</u> Andramed GmbH Schiebwieslenstrasse 18, 72766 Reutlingen Germany. FSC Germany issuance date 29-05-2024 (Original)	AndraBalloon (PTA Balloon Catheter) Class-B Shelf life: 2 years Codes: as per FSC	Approved in Class-B
15.	M/s Intek Corporation, Office # 501-502, Kohistan Towers Mehfooz Road, Saddar Rawalpindi ELI: 00794	<u>Legal Manufacturer:</u> Andramed GmbH Schiebwieslenstrasse 18, 72766 Reutlingen Germany. FSC Germany issuance date 29-05-2024 (Original)	Andra2Balloon (PTA Balloon Catheter) Class- B Shelf life: 2 years Codes: as per FSC	Approved in Class-B
16.	M/s Intek Corporation, Office # 501-502, Kohistan Towers Mehfooz Road, Saddar Rawalpindi ELI: 00794	<u>Legal Manufacturer:</u> Andramed GmbH Schiebwieslenstrasse 18, 72766 Reutlingen Germany. FSC Germany issuance date 29-05-2024 (Original)	AndraStent Aortic (AndraStent Aortic) Class- D Shelf life: 2 years Codes: as per FSC	Approved
17.	Gulfam Brothers Office No. 702, 7 th	<u>Legal Manufacturer:</u> Bioteque Corporation	Bioteq Ureteral Stent Set Ureteral Stent Set, Double J-type	Approved

	Floor, Land Mark Plaza Jail Road, Lahore H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore. ELI-00028	5F-6, No. 23 Sec,1, Change-An E, Road, Taipei 104, Taiwan R.O.C. China FSC: Taiwan Valid till: 10th June,2022 FSC Germany issuance 25-05-2020 510(k) K 033210	Class-C Shelf life: 3 years Codes as per FSC	
18.	Al-Waali Care Concepts, 86-Allama Iqbal Road, chah baba shadiwal street, Garhi Shahu, Lahore. ELI: 00386	Legal Manufacturer: Zhejiang Perfectseal New Material Technology Co., Ltd. A1-1 of # 5 Plot No. 96 Mujin Road, Ningbo High-tech zone, Ningbo City 315000, Zhejiang Province, P. R China. FSC Germany issuance 17-08-2023 (Original)	Perfectseal Topical Tissue Adhesive Class-C Shelf life: 3 years Models: A-001 B-001 C-001	Approved in Class-B
19.	M/s Global Health Care, Office No. 41-A, Street 15 near Foundation School, Race Course Road, Westridge, Rawalpindi. (ELI-00086)	Legal Manufacturer: Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Korea issue date 09-12-2022)	I Chroma™ Troponin T I Chroma™ Troponin T Class-C Shelf life: 20 months Reference no: CFPC-122	Approved
20.	Cure Traders (Smc) Pvt, Ltd, House No. 236, Street No, 01, Sector-F-08 Phase NO, 06, Hayatabad, Peshawar ELI: 00491 AD-III 3107-Kp 18-03-2022	Legal Manufacturer: M/s Sidaphram P.C, 21, Stageiriti & 24 Em. Fili str. 54253, Thessaloniki Greece. FSC: Greece Date of issue: 07/09/2021	Orizon (Preloaded Hydrophobic IOL) Class-C Shelf life: 3 years Code: SDHBPI (CE certificate)	Approved subject to valid ISO 13485 certificate.
21.	HealthBee Projects Private Limited, E-02, Third floor, Jasim Arcade, Plaza 64-65, Lane 1, Square Commercial, Phase 7, Bahria Town, Islamabad. ELI: 00814	Legal Manufacturer: Maxigen biotech Inc. No. 88, Keji 1 st Road., Guishan dist., Taoyuan City 33383, Taiwan R.O.C. FSC Taiwan issuance 14-06-2022	ArtiAid Intra-articulate Injection Class-D Shelf life: 3 years Models: AA-20 AA-25 AA-27	Deferred for provision of valid and notarized ISO 13485 certificate CE, DEC and FSC of any Reference authority as per rules.. The firm applied

			AA-30 AA-35	the models as per FSC but in agreement only one model is mentioned i.e AA-25. Clarification is required.
22.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03- 2024.	Hip Prosthesis System (Femoral Head TB) Class-D Shelf life: 5years Sizes: 28S, 28M, 28L, 28XL, 32S, 32M, 32L, 32XL, 36S, 36M, 36L, 36XL	Deferred for provision of valid and notarized ISO 13485 certificate CE and DEC and original and attested FSC Brand name of the device and FSC of any Reference authority as per rules
23.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03- 2024.	Hip Prosthesis System (Liner 58) Class-D Shelf life: 5years Sizes: 35, 37, 339, 41, 44, 48, 52	Deferred for provision of valid and notarized ISO 13485 certificate CE and DEC and original and attested FSC of any Reference authority as per rules Brand name of the device.
24.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03- 2024.	Hip Prosthesis System (Acetabular cup Mental cup) Class-D Shelf life: 5years Sizes: 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72	Deferred for provision of valid and notarized ISO 13485 certificate CE and DEC and original and attested FSC of any Reference authority as per rules Brand name of the device.

25.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 18-03-2024	DALI 750-Kit W/o NACL (Procedure Pack) Class-C Shelf life: Not provided Art. No: F00010875,9796281,9795201, 9795211, F00009154,9795231, 9795311,MD14021	Approved
26.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 19-03-2024	Monet Kit W/o NACL (Procedure Pack) Class-C Shelf life: Not provided Art. No: F00010879,5008031,9796281, F00009147,F00009148, F00009152,5004821,MD14021	Approved
27.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 18-03-2024	DALI 1000-Kit W/o NACL (Procedure Pack) Class-C Shelf life: Not provided Art. No: F00010876,9796281,9795201, 9795211,F00009154,9795231, MD14021	Approved
28.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 18-03-2024	DALI 1250-Kit W/o NACL (Procedure Pack) Class-C Shelf life: Not provided Art. No: F00010877,9796281,9795201, 9795211,F00009154.9795231, MD14021.	Approved
29.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore.	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. Sites: Fresenius Medical Care AG 61346 Bad Homburg, Germany	DALI 500-Kit W/o NACL (Procedure Pack) Class-C Shelf life: Not provided Art. No: F00010874,9796281,9795201,	Approved

	ELI-00315	FSC Germany issuance 18-03-2024	9795211,F00009154,9795231, 9795301,MD14021	
30.	M. Islam & Sons Near Ghee Mills Dargai Malakand Kpk. ELI-00594	<u>Legal Manufacturer:</u> M/S Changzhou Medical Devices Co., Ltd San He Kou development zone, Zheng, Tianning, 213115 Changzhou, Jiangsu, People Republic of China. FSC issued on 16-04-2024 valid for 2 years	MIS Auto Disable Syringe with Needle. Size & Codes: 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, Shelf Life: 5Years Class B DRAP Application Received Date: August 26 th 2024.	Approved
31.	N. Islam & Sons Near Ghee Mills Dargai Malakand Kpk. ELI-00594	<u>Legal Manufacturer:</u> M/S Changzhou Medical Devices Co., Ltd San He Kou development zone, Zheng, Tianning, 213115 Changzhou, Jiangsu, People Republic of China. FSC issued on 16-04-2024 valid for 2 years	MIS Retractable Safety Syringe with Needle. Size & Codes: 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, Shelf Life: 5Years Class B DRAP Application Received Date: August 26 th 2024.	Approved
32.	O. Islam & Sons Near Ghee Mills Dargai Malakand Kpk. ELI-00594	<u>Legal Manufacturer:</u> M/S Changzhou Medical Devices Co., Ltd San He Kou development zone, Zheng, Tianning, 213115 Changzhou, Jiangsu, People Republic of China. FSC issued on 16-04-2024 valid for 2 years	MIS Infusion set with Needle. Models & Size: 0.4*15RWSB, 0.45*15RWSB26(G*5/8). 0.5*20RWSB(25G*3/4). 0.55*20RWSB(24G*3/4). 0.6*25(23G*1) 0.7*25(22G*3/4). 0.8*28TWSB(21g*11/2), 0.9*28TWSB(20g*11/2), 1.1*30TWSB(19g*11/4), 1.2*30TWSB(18g*11/4). Shelf Life: 5 Years Class B DRAP Application Received Date: August 26 th 2024.	Approved
33.	M. Islam & Sons Near Ghee Mills Dargai Malakand Kpk. ELI-00594	<u>Legal Manufacturer:</u> M/S Henan Tuoren Medical Device Co.,Ltd Main Site: Weiyuan industrial zone, Menggang, Changyuan county, 453400 Henna Province, People Republic of China. FSC China validity	Tuoren IV Cannula. Model: Pen Type, Sizes: As per FSC (14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G) Length: 16mm,19mm,25mm,32mm,45m m,52mm.	Approved subject to submission of fee for each model and revised FSC.

		12-12-2024	<p>Model Butterfly type(wings) with heparin cape, Sizes: As per FSC (14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G) Length: 16mm,19mm,25mm,32mm,45mm,52mm.</p> <p>Model: Injection port type, Sizes: As per FSC (14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G) Length: 16mm,19mm,25mm,32mm,45mm,52mm.</p> <p>Model: Y-type. Sizes: As per FSC (14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G) Length: 16mm,19mm,25mm,32mm,45mm,52mm. Shelf Life: 5 Years Class B DRAP Date of Application Received: March 16th 2024.</p>	
34.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p><u>Legal manufacturer:</u> Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP Suction catheter (Finger Control Connector)-Sterile</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	Approved
35.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p><u>Legal manufacturer:</u> Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP 3-Way Stopcock with Extension Tube –sterile</p> <p>Class-A</p> <p>Shelf life: 5 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	Approved
36.	<p>Mais Medical Products (Pvt) Ltd.</p>	<p><u>Legal manufacturer:</u> Saudi Mais Co. for Medical</p>	<p>SMMP Blood Lines for (Fresenius</p>	Approved

	<p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p>Products (SMMP) Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>Machine) –Sterile</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	
37.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p>Legal manufacturer: Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP Feeding Tube with X ray line (Sterile)</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	Approved
38.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p>Legal manufacturer: Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP Urine Drainage Bag (Sterile)</p> <p>Class-A</p> <p>Shelf life: 5 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	Approved
39.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p>Legal manufacturer: Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP Sodium Bicarbonate for Haemodialysis (for Fresenius Machine)</p> <p>Class-C</p> <p>Shelf life: 3 Years</p> <p>Sizes: Codes and sizes as per FSC</p>	Approved

40.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore</p> <p>ELI- 00693</p>	<p><u>Legal manufacturer:</u> Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address: 3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia</p> <p>FSC: Spain Issued on 5 July 2023 Validity: 5 years</p>	<p>SMMP IV Infusion set with injection bulb vented/unvented-sterile</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: 420-2138 Infusion Set with Injection Bulb 20 Drope /min Vented with Needle Tube L=150Cm 420-2010 Infusion Set with Injection Bulb 20 Drope /min Vented Without Needle Tube L=150Cm 420-2001 Infusion Set with Injection Bulb 20 Drope /min Un-vented With Needle Tube L=150Cm 420-0000 Infusion Set with Injection Bulb 20 Drope /min Un-vented Without Needle Tube L=150Cm 420-6011 Infusion Set with Injection Bulb 60 Drope /min Vented with Needle Tube L=150Cm. 420-6000 Infusion Set with Injection Bulb 60 Drope /min Vented Without Needle Tube L=150Cm. 420-6001 Infusion Set with Injection Bulb 60 Drope /min Unvented with Needle Tube L=150Cm 420-6010 Infusion Set with Injection Bulb 60 Drope /min Unvented Without Needle Tube L=150Cm 420-5000 IV Infusion set for Simco infusion pump</p>	<p>Approved</p>
41.	<p>Mais Medical Products (Pvt) Ltd.</p> <p>Address of</p>	<p><u>Legal manufacturer:</u> Saudi Mais Co. for Medical Products (SMMP)</p> <p>Address:</p>	<p>SMMP IV Infusion burette set with Y injection site –sterile</p>	<p>Approved</p>

	Importer Office No.8 Second Floor Qartaba center 7/8-Jail Road Moazang Chungi, Lahore ELI- 00693	3rd Industrial Area, Al-Kharj Road, Street: 256, Riyadh-14335-7599, Kingdom of Saudi Arabia FSC: Spain Issued on 5 July 2023 Validity: 5 years	Class-B Shelf life: 5 years Model: 428-0100 428-0150 428-0250	
42.	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	Legal Manufacturer: Pacotech Properties Inc. 515 S Milk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Vitalmax 4000 Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Not provided	Deferred for the provision of original documents and FSC having the subject model.
43.	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	Legal Manufacturer: Pacotech Properties Inc. 515 S Milk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Vitalmax 4100 Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Vitalmax 4100	Approved subject to provision of original documents.
44.	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	Legal Manufacturer: Pacotech Properties Inc. 515 S Milk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Vitalmax 800 Plus Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Not provided	Deferred for the provision of original documents and FSC having the subject model.
45.	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	Legal Manufacturer: Pacotech Properties Inc. 515 S Milk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Mini Pack 300 Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Not provided	Deferred for the provision of original documents and FSC having the subject model.
46.	SAAD ENTERPRISES Shop No 3,	Legal Manufacturer: Qingdao DMD Medical technology Co.,Ltd	DMD Liga-Lock Ligating Clips (Ti)	Approved

	Basement Mubarak Plaza Balahisar Road ,Peshawar Mob: 0321-9186070 ELI No.: 00815	No.873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113 Qingdao, People Republic of China. FSC China Valid till: 25-05-2025 EC Valid till: Expired in May'2024, CE confirmation letter is attached for further validity. ISO Valid till: 01-04-2027	Class-C Shelf life: 5 Years Sizes: S, M, ML, L, ST, MT, MLT, LT, MS, Micro	
47.	MTM Associates Suite#F2, First Floor, Zainab Square. 9-10 Block-B. Architects Housing Scheme Lahore-54770 Pakistan. ELI No.: ELI-01112	<u>Legal Manufacturer:</u> Qingdao DMD Medical Technology Co., Ltd No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113 Qingdao, PEOPLE'S REPUBLIC OF CHINA. FSC Valid till: 4-12-2024 EC Validity: Expired in 26-05-2024, CE confirmation letter is attached for further validity. ISO Valid till: 01-04-2027	AORTIC PUNCH Class-B Shelf life: 3 Years Sizes: APP25, APS28, APP36, APS36, APP40, APS40, APP44, APS44, APP48, APS48, APP52, APS52, APP56, APS56, APP60, APS60	Approved subject to submission of Brand name.
48.	MTM Associates Suite#F2, First Floor, Zainab Square. 9-10 Block-B. Architects Housing Scheme Lahore-54770 Pakistan. ELI No.: ELI-01112	<u>Legal Manufacturer:</u> Qingdao DMD Medical Technology Co., Ltd No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113 Qingdao, PEOPLE'S REPUBLIC OF CHINA. FSC Valid till: 4-12-2024 EC Validity: Expired in 26-05-2024, CE confirmation letter is attached for further validity. ISO Valid till: 01-04-2027	LIGATING CLIPS(TI) Class-C Shelf life: 3 Years Sizes: S, M, ML, L, ST, MT, MLT, LT, MS, Micro	Approved subject to submission of Brand name.
49.	MTM Associates Suite#F2, First Floor, Zainab Square. 9-10 Block-B.	<u>Legal Manufacturer:</u> Qingdao DMD Medical Technology Co., Ltd No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113 Qingdao, PEOPLE'S	LIGATING CLIPS(Polymer) Class-C Shelf life: 3 Years	Approved subject to submission of Brand name.

	Architects Housing Scheme Lahore-54770 Pakistan. ELI No.: ELI-01112	REPUBLIC OF CHINA. FSC Valid till: 4-12-2024 EC Validity: Expired in 26-05-2024, CE confirmation letter is attached for further validity. ISO Valid till: 01-04-2027	Sizes: M, ML, L, XL	
50.	MTM Associates Suite#F2, First Floor, Zainab Square. 9-10 Block-B. Architects Housing Scheme Lahore-54770 Pakistan. ELI No.: ELI-01112	<u>Legal Manufacturer:</u> Qingdao DMD Medical Technology Co., Ltd No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113 Qingdao, PEOPLE'S REPUBLIC OF CHINA. FSC Valid till: 4-12-2024 EC Validity: Expired in 26-05-2024, CE confirmation letter is attached for further validity. ISO Valid till: 01-04-2027	LIGATING CLIPS APPLIERS (TITANIUM & POLYMER) Class-A Shelf life: Subject to sterilization Sizes as per FSC	Approved subject to submission of Brand name and fee for the polymer type..
51.	Medilink International, Office No. 609 Pak Medical Center Khyber Bazar, Peshawar ELI: 00456	<u>Legal Manufacturer:</u> Condiner Medical Technology Co., Ltd No. 117 Xueye road, Xinbei Zone, Changzhou, Jiangsu, china. FSC china validity 10-05-2025	Condiner Abdominal Hernia Surgical Mesh Class-C Shelf life: 5 years Specifications as per FSC	Deferred for the submission of following: Valid CE certificate.
52.	Medilink International, Office No. 609 Pak Medical Center Khyber Bazar, Peshawar ELI: 00456	<u>Legal Manufacturer:</u> Jiangsu Webest Medical Equipment Co. Ltd No. 5 Yimgchun Rd, Industrial Park Xuyi, Jiangsu, China. FSC china validity 23-04-2025	IV Cannula for single use IV Cannula for single use Class- B Shelf life: not mentioned Sizes: 14G, 16G, 18G, 20G, 22G, 24G, 26G	Deferred for the submission of following: Attested credentials. Valid CE certificate. Brand name Stability studies and shelf life. Type of cannula.
53.	Medilink International, Office	<u>Legal Manufacturer:</u> Jiangsu Webest Medical	Sterile Syringe for Single use Sterile Syringe for Single use	Deferred for the submission of

	No. 609 Pak Medical Center Khyber Bazar, Peshawar ELI: 00456	Equipment Co. Ltd No. 5 Yimgchun Rd, Industrial Park Xuyi, Jiangsu, China. FSC china validity 23-04-2025	Class- B Shelf life: not mentioned Sizes: 1ml, 10ml, 20ml, 50ml	following: Attested credentials. Valid CE certificate. Brand name Stability studies and shelf life. Type of cannula.
54.	Uniplan Trade International Pvt. Ltd, 132/1 Quaid e Azam Industrial Estate Kot Lakh Pat Lahore. ELI-00132	<u>Legal Manufacturer:</u> Limmer Laser GmbH, Schwarzschildstr. 1, 12489 Berlin Germany. FSC: Berlin Germany. Date of Issuance: 25-06-2024.	UNILAS Touch (CO2 Laser) Class-C Shelf Life: N/A Model: UNILAS Touch One (30W) C20.00.000030 UNILAS Touch One (40W) C20.00.000040 UNILAS Touch Pro (60W) C20.00.000060 UNILAS Touch Pro (70W) C20.00.000070 UNILAS Touch Pro (80W) C20.00.000080	Approved subject to submission of fee for the UNILAS Touch Pro Apply separately for the accessories
55.	FW Distributor Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi ELI:00221	<u>Legal Manufacturer:</u> Coloplast A/S Holtedem 1 3050 Humleback, Denmark <u>Manufacturing Site:</u> i. Coloplast Manufacturing France SAS 9 Avenue Edmond Rostand CS 70218 24206 Sariat- la-Caneda Cedax, France ii. Coloplast Manufacturing US, LLC. 1601 West River Road North Minneapolis, MN 55411 FSC: Denmark Valid till: 20-06-2026	Genesis malleable Penile Prosthesis Rigid Penile Prosthesis Class-C Shelf life: 5 years Codes/models: 519250 519260 519270	Approved subject to submission of valid ISO 13485
56.	FW Distributor Opposite Poonch House, Adamjee Road, Saddar,	<u>Legal Manufacturer:</u> Coloplast A/S Holtedem 1 3050 Humleback, Denmark <u>Manufacturing Site:</u>	TITAN Inflatable Penile Prosthesis Class-C	Approved subject to submission of fee for other two types.

	Rawalpindi ELI:00221	<p>i. Coloplast Manufacturing France SAS 9 Avenue Edmond Rostand CS 70218 24206 Sariat- la-Caneda Cedax, France</p> <p>ii. Coloplast Manufacturing US, LLC. 1601 West River Road North Minneapolis, MN 55411</p> <p>FSC: Denmark Valid till: 20-06-2026</p>	Shelf life: 5 years Codes as per FSC	
57.	<p>Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan</p> <p>R&I Dated: 09/August/2024 Fee Challan No: 286785540065 PKR: 50,000/-</p>	<p>Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de, http://www.melag.com</p> <p>LOA Validity: 23/07/2025 FSC Validity: 24/08/2028</p>	<p>MELATharm 10 Evolution DTB</p> <p>Class: C</p> <p>Shelf life: N/A</p> <p>Model: ME20021</p>	Approved
58.	<p>Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan</p> <p>R&I Dated: 09/August/2024 Fee Challan No: 286785540065 PKR: 50,000/-</p>	<p>Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de, http://www.melag.com</p> <p>LOA Validity: 23/07/2025 FSC Validity: 24/08/2028</p>	<p>MELATharm 10 Evolution DTA</p> <p>Class: C</p> <p>Shelf life: N/A</p> <p>Model: ME20020</p>	Approved
59.	<p>Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan</p> <p>R&I Dated: 09/August/2024 Fee Challan No.: 4680395477 PKR: 50,000/-</p>	<p>Legal Manufacturer: Lasotronix Sp. z o.o. 2A Elektoniczna Street, 05-500 Piaseczno Poland.</p> <p>LOA Validity: 10/08/2025 FSC Validity: 18/03/2028</p>	<p>Diode laser SMART SG3 Medical Diode laser</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Model: SMART SG3</p>	Approved
60.	<p>Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan</p> <p>R&I Dated: 09/August/2024</p>	<p>Legal Manufacturer: Lasotronix Sp. z o.o. 2A Elektoniczna Street, 05-500 Piaseczno Poland.</p> <p>LOA Validity: 10/08/2025 FSC Validity: 18/03/2028</p>	<p>Diode laser SMART SG1 Medical Diode laser</p> <p>Class-C</p> <p>Shelf life: N/A</p>	Approved

	Fee Challan No.: 4680395477 PKR: 50,000/-		Model: SMART SG1	
61.	Radiant Medical (Pvt) Ltd, Address of Importer 06 Sher Shah Block, New Garden Town, Lahore. ELI- 00135 Dossier No. 4935-P	Legal manufacturer: Heyer Medical AG Address: Carl-Heyer-Str. 1/3 53130 Bad Ems / Germany. FSC: Germany Issued 18 August,2023.	Pasithec II Inhalation Anesthesia System Class-C Shelf life: N/A Article no. 112000	Approved
62.	Radiant Medical (Pvt) Ltd, Address of Importer 06 Sher Shah Block, New Garden Town, Lahore. ELI- 00135 Dossier No. 4933-P	Legal manufacturer: Gimmi GmbH Address: Carl-Zeiss-Str. 6 78532 Tuttlingen Germany. FSC: Germany Issued on 06/09/2022	Gimmi® Gimmi Surgical Instruments, Bipolar scissor Class-C Shelf life: N/A Codes: A.9100.18, A.9100.22, A.9100.24, A.9100.28, A.9101.18, A.9101.22, A.9101.24, A.9101.28, A.9105.18, A.9105.24, A.9105.28	Approved
63.	Ameer Sons, Address of Importer 305-A, Upper Mall, Lahore. ELI- 00058 Dossier No. 1954-P	Legal manufacturer: Cooper Vision Manufacturing Ltd, Address: South Point Hamble Southampton SO31 4RF UK. Original FSC: United Kingdom Issued on 20 February, 2020	Biofinity ®XR Toric Soft Contact lenses Class-B Shelf life: 4 Year Sizes: Codes and sizes as per FSC	Approved subject to submission of valid LOA, ISO 13485 and FQA certificates. The letter will be issued after the submission of LoA.
64.	Ameer Sons, Address of Importer 305-A, Upper Mall, Lahore. ELI- 00058	Legal manufacturer: Cooper Vision Manufacturing Ltd, Address: South Point Hamble Southampton SO31 4RF UK. FSC: United Kingdom Issued on 16 April 2019.	AVAIRA VITALITY Soft Contact Lens Class-B Shelf life: 7 Year Sizes: Codes and sizes as per FSC	Approved subject to submission of valid LOA, ISO 13485 and FQA certificates. The letter will be issued after the submission of LoA

	Dossier No. 1955-P			
65.	Ameer Sons, <u>Address of Importer</u> 305-A, Upper Mall, Lahore. ELI- 00058 Dossier No. 1952-P	<u>Legal manufacturer:</u> Cooper Vision Manufacturing Ltd, <u>Address:</u> South Point Hamble Southampton SO31 4RF UK. Original FSC: United Kingdom Issued on 16 April 2019.	AVAIRA VITALITY TORIC Soft Contact Lens Class-B Shelf life: 7 Year Sizes: Codes and sizes as per FSC	Approved subject to submission of valid LOA, ISO 13485 and FQA certificates. The letter will be issued after the submission of LoA
66.	Deejhons Pharma, <u>Address of Importer</u> 185F Block Sabzazar Lahore. ELI- 00976 Dossier No. 5234-P	<u>Legal manufacturer:</u> Eyekon Medical, Inc. <u>Address:</u> 2451 Enterprise Rd Clearwater, Florida USA 33763. Original FSC: USA. Issued on 17 March 2023. Validity: 16 March 2025.	MDR Hydrophilic Acrylic Intraocular Lens Class-C Shelf life: 24 Months Model: MC25B-0UV	Approved
67.	Bio Medics Medical System, <u>Address of Importer</u> F-597, F-Block, Satellite Town, Rawalpindi. ELI- 00022 Dossier No. 1811-P	<u>Legal manufacturer:</u> Fengh Medical Co., Ltd, <u>Address:</u> D3 No. 6 Dongsheng West Road, Jiangyin National High-tech Zone, 214437 Jiangsu, China. FSC: China. Validity: 11 March 2021.	Fengh Disposable Endoscopic Ligating Loop (all models). Class-B Shelf life: 36 Months Codes: FL10, FL20, HL10, HL20	Approved subject to the provision of valid LOA, ISO 13485 and FQA certificates. The letter will be issued after the submission of LoA and verification of Class since per DoC submission it is mentioned IIb which is Class-C and also under MDR it is Class-C device. Also mentioned the type of material, the clip made of.
68.	Bio Medics Medical System, <u>Address of Importer</u> F-597, F-Block, Satellite Town, Rawalpindi.	<u>Legal manufacturer:</u> Fengh Medical Co., Ltd, <u>Address:</u> D3 No. 6 Dongsheng West Road, Jiangyin National High-tech Zone, 214437 Jiangsu, China. FSC: China.	Fengh Disposable Endoscopic Trocar Class-B Shelf life: 36 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after the submission of LoA, CE marking and FSC in the country of origin.

	ELI- 00022 Dossier No. 1836-P	Validity: 11 March 2021.		
69.	Medimage Services 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan ELI No.: 00548	<u>Legal Manufacturer:</u> Being Technology Co., Ltd No. 108 Gongxiang Road Qiandeng Town Kunshan, China FSC China Valid till: 4-Jun- 2025 EC Valid till: Expired in 31- Dec- 2028, CE confirmation letter is attached for further validity. ISO Valid till: 23-Jan-2025	INFANT INCUBATOR BIN-3000A Class-C Shelf life: 5 Years Codes: BIN-3000A	Approved subject to brand name..
70.	Medimage Services 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan ELI No.: 00548	<u>Legal Manufacturer:</u> Being Technology Co., Ltd No. 108 Gongxiang Road Qiandeng Town Kunshan, China FSC China Valid till: 4-Jun- 2025 EC Valid till: Expired in 31- Dec- 2028, CE confirmation letter is attached for further validity. ISO Valid till: 23-Jan-2025	INFANT RADIANT WARMER BRW-3000A Class-C Shelf life: 5 Years Model: BRW-3000A	Approved subject to brand name..
71.	Medimage Services 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan ELI No.: 00548	<u>Legal Manufacturer:</u> Being Technology Co., Ltd No. 108 Gongxiang Road Qiandeng Town Kunshan, China FSC China Valid till: 4-Jun- 2025 EC Valid till: Expired in 31- Dec- 2028, CE confirmation letter is attached for further validity. ISO Valid till: 23-Jan-2025	Phototherapy Equipment BBP-2000B Class-B Shelf life: 5 Years Model: BBP-2000B	Approved subject to brand name..
72.	Medimage Services 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan	<u>Legal Manufacturer:</u> MEDEVO MEDICAL CO., LTD Room201, F/2, Unit 5, Building 10, Courtyard No.20, Kechuang 14 Street, Beijing	Medevo SYRINGE PUMP SPA112 Class-C	Approved

	ELI No.: 00548	Economic and Development Zone, Beijing, China FSC Valid till: 22-04-2025 EC Valid till: Expired in 31-Dec 2028, CE confirmation letter is attached for further validity. ISO Valid till: 02-Nov-2027	Shelf life: 5 Years Model: SPA112	
73.	Medimage Services 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan ELI No.: 00548	Legal Manufacturer: MEDEVO MEDICAL CO., LTD Room201, F/2, Unit 5, Building 10, Courtyard No.20, Kechuang 14 Street, Beijing Economic and Development Zone, Beijing, China FSC Valid till: 22-04-2025 EC Valid till: Expired in 31- Dec 2028, CE confirmation letter is attached for further validity. ISO Valid till: 02-Nov-2027	Medevo INFUSION PUMP IPA112 Class-C Shelf life: 5 Years Model: IPA112	Approved
74.	AK Trader, Address of Importer 123-Canal Bank Housing Scheme, Harbanspura, Lahore. ELI- 01035 Dossier No. 4850-P	Legal manufacturer: Hangzhou Rejoin Mastin Medical Device Co., Ltd, Address: Floors 1 st and 2 nd , 101B, No. 22, Zinyan Road, Economic Technological Development Xone, Linping District, 311100 Hangzhou, Zhejiang, People's Republic China. FSC: China. Validity: 08 January 2024.	Shaver Blade Class-C Shelf life: not provided Sizes: Codes and sizes as per FSC	Deferred for the provision of following: Valid FSC Stability studies and shelf life is not provided. Brief description and all technical documents are missing. No brand name is provided. The submitted name is not found in FSC or any other document.

				ISO 13485 Valid notarized CE certificate
75.	AK Trader, <u>Address of Importer</u> 123-Canal Bank Housing Scheme, Harbanspura, Lahore. ELI- 01035 Dossier No. 4851-P	Legal manufacturer: Hangzhou Rejoin Mastin Medical Device Co., Ltd, Address: Floors 1 st and 2 nd , 101B, No. 22, Zinyan Road, Economic Technological Development Xone, Linping District, 311100 Hangzhou, Zhejiang, People's Republic China. FSC: China. Validity: 08 January 2024.	Anchor Class-C Shelf life: not provided Sizes: Codes and sizes as per FSC	Deferred for the provision of following: Valid FSC Stability studies and shelf life is not provided. Brief description and all technical documents are missing. No brand name is provided. The submitted name is not found in FSC or any other document. ISO 13485 Valid notarized CE certificate
76.	A2Z Medical, <u>Address of Importer</u> 235-Ahmed Block, New Garden Town, Lahore. ELI-01239 Dossier No. 1350-P	Legal Manufacturer: Supermax / Maxter Glove Manufacturing Address: Lot 308, Putra Industrial Park Bukit Rahman Putra 47000 Sungai Buloh, Selangor, Malaysia. Lot 6070, Jalan Haji Abdul Manan, 6 th Mile Off Jalan Meru, 41050, Klang, Selangor, Malaysia. FSC: Malaysia. Validity: 31 July 2026.	Maxwell Rubber Latex Examination Gloves Class-A Shelf Life: 5 years Sizes: S, M, L, XL	Approved subject to submission of type of gloves and revised fee as per new S.R.O
77.	A2Z Medical, <u>Address of Importer</u>	Legal Manufacturer: Supermax / Maxter Glove Manufacturing	Maxwell Sterile Surgical Gloves, Powdered Class-B	Approved subject to submission of revised fee as per new S.R.O

	235-Ahmed Block, New Garden Town, Lahore. ELI-01239 Dossier No. 5377-P	Address: 1. Lot 308, Putra Industrial Park Bukit Rahman Putra 47000 Sungai Buloh, Selangor, Malaysia. 2. Lot 6070, Jalan Haji Abdul Manan, 6 th Mile Off Jalan Meru, 41050, Klang, Selangor, Malaysia. FSC: Malaysia. Validity: 31 July 2026.	Shelf life: 5 Year Sizes not mentioned	
78.	Global Marketing Services 111, Hali Road, Westridge 1, Rawalpindi, Pakistan ELI-00109	Legal Manufacturer: InTec Products, Inc. 332, Xinguang Rd, Xinyang IND.AREA,Haicang Xiamen, 361022 China. WHO pre-qualified ID # 0371-017-00 Date of prequalification 17 May, 2019	Rapid Anti-HCV Test Anti-HCV Test Class-D Shelf life: 24 Months Code: ITP01153-TC40	Approved
79.	Global Marketing Services 111, Hali Road, Westridge 1, Rawalpindi, Pakistan ELI-00109	Legal Manufacturer: InTec Products, Inc. 332, Xinguang Rd, Xinyang IND.AREA,Haicang Xiamen, 361022 China. WHO pre-qualified ID # 0371-017-00 Date of prequalification 17 May, 2019	Rapid Anti-HCV Test Anti-HCV Test Class-D Shelf life: 24 Months Code: ITP01152-TC25	Approved
80.	Medequips SMC (Pvt.) Ltd. 30-Shahrah e Quaid e Azam, Lahore. ELI- 00362	Legal Manufacturer: Canon Medical System Corporation 701-Yangi-Cho, Saiwai-Ku, Kawaki-shi- Kanagawa 212-0015 JAPAN. FSC Japan Valid 24-07-2029	APLIO SYSTEM Diagnostic Ultrasound System Class-B Shelf life: Expected service life will be 4 years on the operation manual but TMSO can continue to supply it for seven years after the last installation of the UL-system. Models: TUS-Ai600, TUS-Ai700, TUS- Ai800, TUS-Ai900, CUS-AA450 CUS-AA550, CUS-AA000, CUS- AFL00, CUS-AGG00, CUS- AME00	Approved subject to submission fee for different models as family.

81.	Medequips SMC (Pvt.) Ltd. 30-Shahrah e Quaid e Azam, Lahore. ELI- 00362	<u>Legal Manufacturer:</u> Canon Medical System Corporation 701-Yangi-Cho, Saiwai-Ku, Kawaki-shi-Kanagawa 212-0015 JAPAN. Free sale Germany valid till Valid 24-07-2024	VANTAGE SYSTEM Magnet Resonance Imaging System Class-B Shelf life: 5 years. Models: MEXL-1503/S5, MRT-2020/G1, MRT-1510, MRT-1550, MRT-3020	Approved subject to submission fee for different models as family.
82.	M.A Tech, 18-G, Upper Basement Memona Centre Mouji Draya Road Fareed Court Lahore ELI: 00593	<u>Legal Manufacturer:</u> Beijing Ruicheng Medical Supplies Co., Ltd. No.13 Yanqi Economic Development Zone, Huairuo District, Beijing FSC: China Valid till: 18-07-2024	CareSafe (Blood Lancets) Class-B Shelf Life: 5 years Code: 28GI, 30GI, 28GIV, 30GIV	Approved subject to submission valid CE certificate.
83.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	<u>Legal Manufacturer:</u> Shijiazhuang Kang Weishi Medical Instrument Co, Ltd No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China. Validity: 04 August 2022.	KWS No Additive Tube: 0.5ml/ 1ml/ 1.5ml/ 2ml/ 2.5ml/ 3ml/ 3.5ml/ 4ml/ 4.5ml/ 5ml/ 5.5ml/ 6ml/ 6.5ml/ 7ml/ 8ml/ 9ml/ 10ml, Class-A Shelf life: 24 Months	Approved The letter willsued after submission of valid LOA, FSC, ISO 13485 and CE certificate
84.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	<u>Legal Manufacturer:</u> Shijiazhuang Kang Weishi Medical Instrument Co, Ltd Address: No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China. Validity: 04 August 2022.	KWS Coagulation Tube: 0.5ml/ 1ml/ 1.5ml/ 2ml/ 2.5ml/ 3ml/ 3.5ml/ 4ml/ 4.5ml/ 5ml/ 5.5ml/ 6ml/ 6.5ml/ 7ml/ 8ml/ 9ml/ 10ml Class-A Shelf life: 24 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
85.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	<u>Legal Manufacturer:</u> Shijiazhuang Kang Weishi Medical Instrument Co, Ltd No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China.	KWS Separation Gel: 0.5ml/ 1ml/ 1.5ml/ 2ml/ 2.5ml/ 3ml/ 3.5ml/ 4ml/ 4.5ml/ 5ml/ 5.5ml/ 6ml/ 6.5ml/ 7ml/ 8ml/ 9ml/ 10ml Class-A	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485

		Validity: 04 August 2022.	Shelf life: 24 Months Sizes: Codes and sizes as per FSC	
86.	Mian Scientific Corporation (Pvt) Ltd, Address of Importer 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Shijiazhuang Kang Weishi Medical Instrument Co, Ltd Address: No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China. Validity: 04 August 2022.	KWS EDTA-K₃ Tube: 0.5ml/ 1ml/ 1.5ml/ 2ml/ 2.5ml/ 3ml/ 3.5ml/ 4ml/ 4.5ml/ 5ml/ 5.5ml/ 6ml/ 6.5ml/ 7ml/ 8ml/ 9ml/ 10ml. Class-A Shelf life: 24 Months	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
87.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Shijiazhuang Kang Weishi Medical Instrument Co, Ltd No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China. Validity: 04 August 2022.	KWS Heparin Lithium Tube: 0.5ml/ 1ml/ 1.5ml/ 2ml/ 2.5ml/ 3ml/ 3.5ml/ 4ml/ 4.5ml/ 5ml/ 5.5ml/ 6ml/ 6.5ml/ 7ml/ 8ml/ 9ml/ 10ml Class-A Cluster Shelf life: 24 Months	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
88.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Shijiazhuang Kang Weishi Medical Instrument Co, Ltd No. 95, Yuanshi County, Shijiazhuang City, Hebei Province, China. FSC: China. Validity: 04 August 2022.	KWS Sodium Citrate 1:4 Tube: 0.5ml/ 1.28ml/ 1.6ml/ 2ml/ 2.4ml/ 3ml/ 3.2ml/ 4ml/ 5ml/ 6ml/ 7ml/ 8ml/ 9ml/ 10ml Class-A Shelf life: 24 Months	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
89.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Demophorius Limited, 196 Archbishop Makarios III Avenue Limmassol, 3030 Cyprus. FSC: Cyprus. Issuance date: 10-Feb, 2020	D-Vac Z Gel & clot activator Serum Sep Class-A Cluster Shelf life: 24 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
90.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan	Legal Manufacturer: Demophorius Limited 196 Archbishop Makarios III Avenue Limmassol, 3030 Cyprus. FSC: Cyprus.	D-Vac K2 E EDTA (K2) Class-A Shelf life: 24 Months	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485

	ELI-00442	Issuance date: 10-Feb,2020	Sizes: Codes and sizes as per FSC	
91.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Demophorius Limited 196 Archbishop Makarios III Avenue Limmassol, 3030 Cyprus. FSC: Cyprus. Issuance date: 10-Feb,2020	D-Vac K3 E EDTA (K3) Class-A Shelf life: 24 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
92.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Demophorius Limited 196 Archbishop Makarios III Avenue Limmassol, 3030 Cyprus. FSC: Cyprus. Issuance date: 10-Feb,2020	D-Vac Z Serum clot activator Class-A Shelf life: 24 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
93.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad, 38030, Pakistan ELI-00442	Legal Manufacturer: Demophorius Limited 196 Archbishop Makarios III Avenue Limmassol, 3030 Cyprus. FSC: Cyprus. Issuance date: 10-Feb,2020	D-Vac 4NC ESR Sodium Citrate 3.8% Liquid Class-A Shelf life: 24 Months Sizes: Codes and sizes as per FSC	Approved The letter will be issued after submission of valid LOA, FSC, ISO 13485
94.	Zenith International,Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi,Pakistan (ELI-00090)	Legal Manufacturer: M/s Shenzhen Homed Medical Device Co., Ltd, Manufacturing Site: Room 1601-1614, A Building, Jinxiu III, No.85 Hudi Pai, Songxuan Community, Guanhu Street, Longhua District, Shenzhen, China FSC: China Validity: 19-10-2025 Applied on basis CE Certificate.	PERFECT Piston Compressor Nebulizer Class B Shelf Life: 05 years Model: JLN2305AS	Approved.
95.	Royal Enterprise, SH5, Karimji Building, Opp HBL North Napier	Legal Manufacturer M/s Jiangsu Folee Medical Equipment Co. Ltd. China. Manufacturing Site	Folee Portable Phlegm Suction Unit Class B	Approved.

	Road, Karachi. (ELI-00062)	No.16 Xingmao Road, Zhenjiang City, Jiangsu Province, China. FSC China (APOSTILLE) Valid till 07.01.2026 Marketing Authorization Letter: LOA Valid till 22.03.2028. Applied on basis CE Certificate.	Shelf Life: N/A Model: H003-D, H003-F	
96.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Haiyan Kangyuan Medical Instrument Co,Ltd China. FSC China: Valid till: 03-09-2024	New Golden Nasal Oxygen Cannula Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
97.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	New Golden Urine Bag Class-A Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
98.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	New Golden Three Way Stopcock Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
99.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	New Golden Heparin Cap Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
100.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN Blood Lancet Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC

101.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN Umbilical Cord Clamp Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
102.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN Disposable Shoe Cover Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
103.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN I.V. Flow Regulator Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
104.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN Latex Surgical Gloves Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
105.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd. China. FSC China: Validity 03-09-2024	NEW GOLDEN Latex Examination Gloves Class-B Shelf life: 5 years Code & Sizes: As per FSC	Approved The letter will be issued after submission of FSC
106.	Batla Impex, Shop No A Rehman Chamber Medicine Street No 2 Marriot Road, Karachi. (ELI-00170)	Legal Manufacturer: TOP GLOVE SDN BHD, Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru 41050 Kalang, Selangor D.E. Malaysia. FSC Malaysia: Validity 30-04-2026	GOLDEN Latex Examination Gloves Class-A Shelf life: 5 years Code & Sizes: As per FSC	Approved.

107.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi. (ELI-00084)	LEGAL MANUFACTURER M/s Red Cell Biyoteknoloji A.S. SERIFALI MAHALLESI BEYIT SOKAK NO:66/4 UMRANIYE/ ISTANBUL. FSC TURKEY: Valid till: 24.01.2025 Applied on CE marking basis.	RED CELL Blood Grouping Gel System Class D Shelf Life: 24 Months Codes: As per FSC of Turkey (Cert. No. 300149)	Approved subject to submission of valid and appostille FSC of any RRA.
108.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi. (ELI-00084)	LEGAL MANUFACTURE R M/s Red Cell Biyoteknoloji A.S. SERIFALI MAHALLESI BEYIT SOKAK NO:66/4 UMRANIYE/ ISTANBUL. FSC TURKEY: Valid till: 24.01.2025	RED CELL Gel Card Centrifuge, RED CELL Gel Card Incubator, RED CELL Gel Card Reader, RED CELL LISS 500ml Class A Shelf Life: 24 Months Codes: As per FSC of Turkey (Cert. No. 300149)	Approved RED CELL Gel Card Centrifuge and firm shall submit fee for other products before the issuance of Registration/Enlistment letter.
109.	Kiswa Cares, Office No.07, Gulf Plaza, Chandni Chowk, Rawalpindi (ELI-00211)	<u>Legal Manufacturer:</u> Avizor S.A Avenida de la Innovacion,2-28919, Leganes-Spain. <u>FSC:</u> Spain Date of Issuance:16-04-2024	AVIZOR LACRIFRESH OCU-DRY PRESERVATIVE FREE (Sodium Hayaluronate 0.30% EYE DROPS) (Wetting and Lubricating Solution for dry eyes and all types of contact lenses) Class C Shelf Life: 03 years Codes/Sizes: 1.Single Vial 0.4ml Pack size 20*0.4 ml 2.OSD System (10ml)	Approved.
110.	Kiswa Cares, Office No.07, Gulf	<u>Legal Manufacturer:</u>	AVIZOR LACRIFRESH OCU-DRY	Approved.

	Plaza, Chandni Chowk, Rawalpindi (ELI-00211)	Avizor S.A Avenida de la Innovacion,2-28919, Leganes-Spain. <u>FSC:</u> Spain Date of Issuance: 16-04-2024	PRESERVATIVE FREE (Sodium Hayaluronate 0.20% EYE DROPS) (Wetting and Lubricating Solution for dry eyes and all types of contact lenses) Class C Shelf Life: 03 years Codes/Sizes: 1.Single Vial 0.4ml Pack size 20*0.4 ml 2.OSD System (10ml)	
111.	Kiswa Cares, Office No.07, Gulf Plaza, Chandni Chowk, Rawalpindi (ELI-00211)	<u>Legal Manufacturer:</u> Avizor S.A Avenida de la Innovacion,2-28919, Leganes-Spain. <u>FSC:</u> Spain Date of Issuance: 16-04-2024	AVIZOR LACRIFRESH MOISTURE PRESERVATIVE FREE (Sodium Hayaluronate 0.10% EYE DROPS) (Wetting and Lubricating Solution for dry eyes and all types of contact lenses) Class C Shelf Life: 03 years Codes/Sizes: 1.Single Vial 0.4ml Pack size 20*0.4 ml 2.OSD System (10ml), (15ml).	Approved.
112.	Kiswa Cares, Office No.07, Gulf Plaza, Chandni Chowk, Rawalpindi (ELI-00211)	<u>Legal Manufacturer:</u> Avizor S.A Avenida de la Innovacion,2-28919, Leganes-Spain. <u>FSC:</u> Spain Date of Issuance: 16-04-2024	AVIZOR LACRIFRESH ALOE PRESRVATIVE FREE ((Hypromelose & Aloe vera EYE DROPS) (Wetting and Lubricating Solution for dry eyes and all types of contact lenses) Class C Shelf Life: 03 years Codes/Sizes: 1.Single Vial 0.4ml Pack size	Approved.

			20*0.4 ml 2.OSD System (10ml), (15ml).	
113.	SULTANSONS, 133, KUTCHI GALI NO. 1, MARRIOT ROAD, KARACHI (ELI- 00051)	LEGAL MANUFACTURER: Jiangsu Kangbao Medical Equipment Co., Ltd., 78#, North Suzhong Road, Baoying Yanngzhou, Jiangsu Province, P.R. China.	CLASSIC + IV CATHETER PEN TYPE Class: B Shelf Life: 05 Years (SIZES: 26G, 24G, 22G, 20G, 18G, 16G, 14G) FSC: MHRA UK: Valid till 18.07.2026	Approved.
114.	Aqib Trading Company (Pvt) Limited, Main GT Road Adamzai Akora Khattak Distt. Nowshera KPK	LEGAL MANUFACTURER: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province, China.	AT-Tube (Heparin Lithium Vacuum Blood Collection Tube) Class A Size: 3 ml FSC: Valid Till 11.01.2026	Approved.
115.	Aqib Trading Company (Pvt) Limited, Main GT Road Adamzai Akora Khattak Distt. Nowshera KPK	LEGAL MANUFACTURER: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province, China.	AT-Tube (EDTAK3 Vacuum Blood Collection Tube) Class A Size: 3 ml FSC: Valid Till 11.01.2026	Approved.
116.	Aqib Trading Company (Pvt) Limited, Main GT Road Adamzai Akora Khattak Distt. Nowshera KPK	LEGAL MANUFACTURER: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province, China.	AT-Tube (Separating Gel Vacuum Blood Collection Tube) Class A Size: 3 ml FSC: Valid Till 11.01.2026	Approved.
117.	M/S Lab Link Enterprises, 221-H, Block-2 PECHS Karachi (ELI-00007)	Legal Manufacturer: Yangzhou Medline Industry Co., Ltd,	Medline Sterile Infusion Set With Y Port Class B	Approved.

		<p>No. 108 Jinshan Road, Economic Development Zone, Yangzhou ,225009, Jiangsu P.R China.</p> <p>FSC: Country : China Validity: 10-01-2026</p> <p>LOA Validity: 17-03-2027</p> <p>Applied on the basis of CE certification.</p>	<p>Shelf Life: 05 years</p> <p>Codes/Sizes: Not provided</p>	
118.	M/S Lab Link Enterprises, 221-H, Block-2 PECHS Karachi (ELI-00007)	<p>Legal Manufacturer: Yangzhou Medline Industry Co., Ltd, No. 108 Jinshan Road, Economic Development Zone, Yangzhou ,225009, Jiangsu P.R China.</p> <p>FSC: Country : China Validity: 10-01-2026</p> <p>Applied on the basis of CE certification.</p>	<p>Medline Sterile Infusion Set With Y Port</p> <p>Class B</p> <p>Shelf Life: 05 years</p> <p>Codes/Sizes: Not provided</p>	Approved.
119.	M/S Lab Link Enterprises 221-H, Block-2 PECHS Karachi (ELI-00007)	<p>Legal Manufacturer: Yangzhou Medline Industry Co., Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou ,225009,Jiangsu P.R China.</p> <p>FSC: Country : China Validity: 10-01-2026</p> <p>Applied on the basis of CE certification.</p>	<p>Medline I.V. Catheter PEN TYPE (I.V. Cannula Pen Type)</p> <p>Class B</p> <p>Shelf Life: 05 years</p> <p>Sizes: G14,G16,G18,G20,G22,G24.</p>	Approved.
120.	M/S Lab Link Enterprises 221-H, Block-2 PECHS Karachi (ELI-00007)	<p>Legal Manufacturer: Yangzhou Medline Industry Co., Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou ,225009,Jiangsu P.R China.</p>	<p>Medline I.V. Catheter With Injection Port & Wings (I.V. Canulla With Injection Port & Wings)</p> <p>Class B</p> <p>Shelf Life: 05 years</p>	Approved.

		FSC: Country : CHINA Validity: 10-01-2026 Applied on the basis of CE certification.	Sizes: G14,G16,G18,G20,G22,G24.	
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DEFERRED CASES (IMPORT & LOCAL)

Sr. No.	Name & Address of the importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturer	Name of Medical Devices/ Shelf life /Class & codes / sizes (if any)	Decision
1.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2770 Evaluator AD-III	Legal Manufacturer: JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Double) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-4018	Approved subject to clarification of the applied name in form 7A and reference country FSc
2.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2676 Evaluator AD-III	Legal Manufacturer: JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Triple) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5307	Approved subject to clarification of the applied name in form 7A and reference country FSc
3.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2677 Evaluator	Legal Manufacturer: JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Quadruple) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5408	Approved subject to clarification of the applied name in form 7A and reference country FSc

	AD-III			
4.	M/s S. Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2791 Evaluator AD-III	Legal Manufacturer: JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Single) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5004	Approved subject to clarification of the applied name in form 7A and reference country FSc
5.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -56-	Legal Manufacturer & Mfg. site: M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Single (250ml) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC. Reg. No. 011442 Valid Till: 09-03-2019	Approved subject to clarification of the applied name in form 7A and reference country FSc
6.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -57-	Legal Manufacturer & Mfg. site: M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Triple (500ml + 300mlx2) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC. Reg. No. 011444 Valid Till: 09-03-2019	Deferred for provision of the reference country FSC as per Applied name
7.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -58-	Legal Manufacturer & Mfg. site: M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Quadruple (500ml + 300mlx3) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC Reg. No. 011445 Valid Till: 09-03-2019	Deferred for provision of the reference country FSC as per Applied name
8.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -59-	Legal Manufacturer & Mfg. site: M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Double (500ml + 300ml) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC Reg. No. 011443 Valid Till: 09-03-2019.	Deferred for provision of the reference country FSC as per Applied name
9.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi	Legal Manufacturer & Mfg. site: M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore	JMS Blood Collection Bag Single (500ml) Class-D Shelf Life: 03-years.	Approved subject to clarification of the applied name in form 7A and reference country FSc

	(ELI-00078) -60-	FSC Singapore Issuance Date (11-10-2019)	Codes & Sizes as per FSC Reg. No. 01122 Valid Till: 26-02-2020.	
10.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan ELI: 00078 [1380-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	Berichrom ® F XIII Berichrom F XIII Code: OWSUII CLASS-C Shelf Life: 24 months	Approved
11.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1233-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	Coagulation Factor IX Deficient Plasma (Coagulation Factor IX Deficient Plasma) Code: OTXX17 Class- C Shelf Life: 24 months	Approved
12.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1234-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance	Coagulation Factor VIII Deficient Plasma (Coagulation Factor VIII Deficient Plasma) Code: OTXW17 Class- C Shelf Life: 24 months	Approved

		date 19.01.2023		
		Scam LOA issuance date 13.12.2022 valid for three years		
13.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1232-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	Coagulation Factor II Deficient Plasma Code: OSGR13 CLASS- C Shelf life: 24 months	Approved
14.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1236-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	Coagulation Factor V Deficient Plasma Code: ORSM19 Class-C Shelf Life: 18th months	Approved
15.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1309-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Coagulation Factor X Deficient Plasma Code: OTXY13 Class: C Shelf Life 24 months	Approved

		Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years		
16.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1381-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	Pathromtin ® SL Reagent Code: OQGS29 OQGS35 Class: C Shelf Life: 24 months	Approved
17.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1313-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023 Scam LOA issuance date 13.12.2022 valid for three years	BC von Willebrand Reagent Code: OUBD37 Class: C Shelf Life: 24 months	Approved
18.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan [1181-K] Evaluator	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany	Thromborel® S Reagent Human Thromboplastin containing calcium Codes: OUHP29 OUHP49	Approved

	AD-II	<p>Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023</p> <p>Scam LOA issuance date 13.12.2022 valid for three years</p>	<p>Class-C</p> <p>Shelf life: OUHP29: 24 months</p>	
19.	<p>M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan</p> <p>[1308-K] Evaluator AD-II</p>	<p>Legal Manufacturer and Manufacturing Site:</p> <p>Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany</p> <p>FSC (scanned copy): Germany</p> <p>Date of issue: 29-04-2019 Original scan copy of Embassy attested Germany FSC issuance date 19.01.2023</p> <p>Scam LOA issuance date 13.12.2022 valid for three years</p>	<p>Test Thrombin Reagent</p> <p>Code: OWHM13</p> <p>Class-C</p> <p>Shelf Life: 24 months</p>	Approved

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