



No.F.4-9/2024-MD (M-72)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 29th October, 2024

Subject: **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 72nd meeting held on 11th & 12th September, 2024 and the Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below: -

Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision
1.	M/s Kamion Pharma, Plot No. G/4-C, SITE Super Highway Phase-II, Karachi (ELM-0070)	Kamiprime Cotton Wool BPC Absorbent Cotton Wool BPC	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the prescribed fee for grant of the required section.
2.	Crespak Medical Industries, 8th KM, Manga Raiwind Road, Lahore. ELM-0004	Engel Plus Surgical Tape	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
3.	Crespak Medical Industries, 8th KM, Manga Raiwind Road, Lahore. ELM-0004	Engel Plus Disposable Stopper Heparin Cap injection stopper with luer	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
4.	Crespak Medical Industries, 8th KM, Manga Raiwind Road, Lahore. ELM-0004	Engel Plus Umbilical Cord Clamp	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
5.	3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha. ELM-0026	Lifemed Disposable Urine Bag (3NLUB)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.


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6.	3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026)	Lifemed Disposable Contrast Powder (3NLCP)	Deferred the case for provision of composition of the applied product.
7.	3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026)	Lifemed Disposable Breathing Set (3NLDBS)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
8.	3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026)	Lifemed Disposable Umbilical Cord Clamp (3NLUCC)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
9.	Byonyks Private Limited, 18-km, Multan Road, Behind Highnoon Laboratories (Pvt) Limited, Lahore. ELM-0056	Byonyks Disinfection Cap	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
10.	Finetex Cotton Industry, Near Dera Sahi Singh, 3-KM, G.T. Road, Kamoke, District Gujranwal (DML-000741)	Doctor's Abdominal Lab Sponges Abdominal / Lab Sponges X-Ray Detectable (Sterile BP Type II)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.
11.	Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi	R-test Mpox Ag Rapid test Monkey pox virus Ag Rapid test	Deferred for provision of evidence of the any of such product available in the reference regulatory authority as per Medical devices Rules, 2017.
12.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	Power Disposable High Pressure Angiographic Syringe	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
13.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	Inflator Plus Disposable Inflation Device Kit	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.

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14.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	CVCATH Disposable Venous Catheter kit	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
15.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	Soft Lumen Disposable Bypass Tubing	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
16.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	DJ-UORO Disposable Ureteral Stent	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
17.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	FAST TRANSDUCER Disposable Pressure Transducer Kit (Double Chamber)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
18.	Nisa S.F (Pvt) Ltd, 10 Km, Muridke-Shiekhupura Road, Shiekhupura.	FAST TRANSDUCER Disposable Pressure Transducer Kit (Single Chamber)	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval of the required section.
19.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051)	MB-Tulle Framycetin Sulphate BP 1%	Deferred the case for confirmation of manufacturing facility. The firm is advised to apply on Form-1 with the required fee for the approval the required section.

2. It is requested to furnish the requisite information/documents within 30 days after uploading of this letter on official website of DRAP.


(AYYAZ AHMAD) 29/10/24
Additional Director (MDMC)/
Secretary MDB



No.F.4-9/2024-MD (M-72)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 29th October, 2024

Subject: - **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO IMPORT – SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF.**

The applications of following applicants were considered by Medical Device Board (MDB) in its 72nd meeting held on 11th & 12th September, 2024 and the Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below: -

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision
(I)	(II)	(III)	(IV)	(V)
1.	M/s Izhar Enterprises, P-39 Backside hameed Palace Street No. 1, Garden Colony, Faisalabad	Legal Manufacturer M/s Super Health Medical (Qingdao) Co., Ltd. (Manufacturing site) No. 236, Heyuan Road, High-Tech Zone, Qingdao 266510 Shandong P.R China	Prime Disposable Intravenous Catheter with Stopper	Deferred for the provision of following: <ul style="list-style-type: none">• Updated CE certificate.• Shelf life and Stability studies.• Essential Principle checklist of the applied device.• Labels and Brochures.• Manufacturing and QC details and validation studies.
2.	M/s Tek Enterprises Office No. MZ-9 Al-Hafeez Heights 65-D Sir Syed Road Gulberg III, Lahore .	Legal Manufacturer Asahi Intecc Co, Ltd. Japan Manufacturing site <ul style="list-style-type: none">• M/s Asahi Intecc Co, Ltd. Japan 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan.• M/s Asahi Intecc Hanoi Co. Ltd. G03 Thang Long Industrial Park, Dong Anh Dist., Hanoi, Ha Noi, Thanh Pho, 001, Vietnam.• M/s Asahi Intecc (Thailand) co., Ltd., 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand	ASAHI EXTENTION WIRE	Deferred for the provision of clarification of Class of medical device as in the notified body confirmation letter, it is mentioned as Is which means Class-A..
3.	M/s Raffay Associates, Office NO, 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi	Legal Manufacturer M/s STARmed Co., Ltd, B-dong, 4F&12F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si, Gyeonggi-do, Korea	VIVA RF Generator	Deferred for the provision of following: <ul style="list-style-type: none">• Updated CE certificate.• Original, valid and attested FSC of Netherland.

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4.	M/s Moon Enterprises, 324 Rewaz Garden, Lahore	Legal Manufacturer: M/s Atlas Medical, Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas Anti-Human Globulin kit	Deferred for the provision of updated documents and FSC of Germany.
5.	M/s Moon Enterprises, 324 Rewaz Garden, Lahore	Legal Manufacturer: M/s Atlas Medical, Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas CRP Latex Test Kit	Deferred for the provision of updated documents and FSC of Germany
6.	M/s Moon Enterprises, 324 Rewaz Garden, Lahore	Legal Manufacturer: M/s Atlas Medical, Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan.	Atlas Bovine Albumin	Deferred for the provision of updated documents and FSC of Germany.
7.	M/s Moon Enterprises, 324 Rewaz Garden, Lahore	Legal Manufacturer: M/s Atlas Medical, Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas D-Dimer Latex Test Kit	Deferred for the provision of updated documents and FSC of Germany.
8.	M/s Moon Enterprises, 324 Rewaz Garden, Lahore	Legal Manufacturer: M/s Guangzhou iCare Medical Technology Co., Ltd., First Floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area, China	ICARE Blood Lancet	Deferred for the provision of updated documents and FSC of Germany.

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9.	M/s Medical Equipment & Systems, 60/61, F.C.C. Syed Maratib Ali Road, Gulberg-4, Lahore.	Legal Manufacturer: M/s ZOLL Circulation Inc., 2000 Ringwood Avenue, San Jose California, USA	TherOx SSO2 Catheter	Deferred for the provision of original attested/notarised copy of Design examination, valid FQA and FSC.
10.	M/s Medical Equipment & Systems, 60/61, F.C.C. Syed Maratib Ali Road, Gulberg-4, Lahore.	Legal Manufacturer: M/s ZOLL Circulation Inc., 2000 Ringwood Avenue, San Jose California, USA	TherOx DownStream Console	Deferred for the provision of original attested/notarised copy of Design examination, valid FQA and FSC.
11.	M/s Medical Equipment & Systems, 60/61, F.C.C. Syed Maratib Ali Road, Gulberg-4, Lahore.	Legal Manufacturer: M/s ZOLL Circulation Inc., 2000 Ringwood Avenue, San Jose California, USA	TherOx Down Stream Cartridge	Deferred for the provision of original attested/notarised copy of Design examination, valid FQA and FSC.
12.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.	Legal Manufacturer: M/s G-Flex Europe SPRL, 20Rue De l'industrie 1400 – Nivelles, Belgium	Sphincterotomes/Pa pillotomes (GTome2®)	Deferred for provision of original documents including LOA, ISO 13485 and FQA/CE marked certificates.
13.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.	Legal Manufacturer: M/s G-Flex Europe SPRL, 20Rue De l'industrie 1400 – Nivelles, Belgium	Disposable Hemoclips (SAFECLIP®)	Deferred for provision of original documents including LOA, ISO 13485 and FQA/CE marked certificates.
14.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.	Legal Manufacturer: M/s G-Flex Europe SPRL, 20Rue De l'industrie 1400 – Nivelles, Belgium	Endoscopic Drainage Stents, Biliary stents	Deferred for provision of original documents including LOA, ISO 13485 and FQA/CE marked certificates
15.	M/s Cardiac Care, 848-C Shadman -1, Lahore	M/s Pacific Hospital Supply Co., Ltd., 4F No.160, Daye Road, Beitou District 112 Taipei, Taiwan	Free Trachea Closed Suction Set	Deferred for the provision of original valid LOA, valid FSC, ISO 13485 and FQA certificates.
16.	M/s Cardiac Care, 848-C Shadman -1, Lahore	M/s Hsiner Co. Ltd., 312, Jhongshan Rd, Shengang Dist, Taichung 429, Taiwan	Anesthesia and Breathing Circuit	Deferred for the provision of original valid LOA, valid FSC, ISO 13485 and FQA certificates.
17.	M/s Cardiac Care, 848-C Shadman -1, Lahore	M/s Hsiner Co. Ltd., 312, Jhongshan Rd, Shengang Dist, Taichung 429, Taiwan	Rebreathing Bag	Deferred for the provision of original valid LOA, valid FSC, ISO 13485 and FQA certificates.
18.	M/s Easha Enterprises, 2B-04 Third Floor, Adyala Towers, Adyala Road, Rawalpindi	Legal Manufacturer: M/s Biomedica Mexicana, Calzada Ermita Iztapalapa No.855 Colonia Santa Isabel Industrial, CP 09820, Mexico	Biomed® CSF Flow Shunt Control Valve Burr-Hole	Deferred for the provision of FSC of any reference country or CE marked document and design examination certificate since the device falls in class-D.

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19.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite Typhoid IgG-IgM Rapid test	Deferred for the provision of updated documents.
20.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite HEV IgM Rapid Test	Deferred for the provision of updated documents.
21.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite HAV IgG-IgM Combo Rapid Test	Deferred for the provision of updated documents.
22.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite H.Pylori Ab Combo Rapid Test	Deferred for the provision of updated documents.
23.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite RF Rapid Test	Deferred for the provision of updated documents.
24.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite Typhoid IgG-IgM Combo Rapid Test	Deferred for the provision of updated documents
25.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK Biotech, Inc. 13855 STOWE Dr. Poway, California USA.	Onsite HIV 1/2 Ab Plus Combo Rapid Test	Deferred for the provision of updated documents
26.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: Wuxi BioHerm's Bio& Medical Technology CO, Ltd.	BioHerm's Glycohemoglobin Test Kit	Deferred for the provision of updated documents.
27.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s ERBA Lachema s.r.o	ERBA XI-200 Chemistry Analyzer	Deferred for the provision of updated documents.
28.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s ERBA Lachema s.r.o	ERBA Chem-7 Chemistry Analyzer	Deferred for the provision of updated documents.
29.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein T4 Fast Test Kit	Deferred for the provision of updated documents.
30.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein TSH Fast Test Kit	Deferred for the provision of updated documents.
31.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein HbA1c Fast Test Kit	Deferred for the provision of updated documents

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32.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein CK-MB/cTnI/Myo Fast Test Kit	Deferred for the provision of updated documents.
33.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein LH Fast Test Kit	Deferred for the provision of updated documents.
34.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein FSH Fast Test Kit	Deferred for the provision of updated documents.
35.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein Troponin-T Fast Test Kit	Deferred for the provision of updated documents.
36.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein CK-MB Fast Test Kit	Deferred for the provision of updated documents.
37.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein CK-MB/cTnI Fast Test Kit	Deferred for the provision of updated documents.
38.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer: M/s Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein Tpsa Fast Test Kit	Deferred for the provision of updated documents.
39.	M/s Contraceptives Pakistan (Pvt) Ltd. Office No. 4A, Street No. 1, 116 Apartments Shah Jamal, Lahore.	M/s Corporate Channels India Pvt. Ltd, 1590-1600, Village Paldi, Post Loyara, P.O. Badgaon, Udaipur 313001 Rajasthan, India	EVE'S TCu380A IUCD	Deferred for the clarification of Brand name and provision of valid ISO 13485 certificate
40.	M/s B.N Tradings Company, Makkah Tower, Office No.207,2 nd Floor, Namak Mandi, Peshawar.	Legal Manufacturer: M/s Jiangsu Webest Medical Products Co., Ltd Manufacturing site: Adress No,5, Ying Chun Road, industrial Park.21700 Xuyi, Jiangsu Province, No,18, ying Chun East Road, Industrial Park,211700 Xuyi, Jiangsu Province, Peoples Republic of China.	BESTLIFE I.V.Cannula for Single Use	Deferred for confirmation of type of cannula and provision of revised form 7 A accordingly.
41.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	M/s KARL STORZ SE & CO. KG, Dr.-Karl-Storz-StraBe 34 78532 Tuttlingen, Germany.	KARL STORZ Endoscopic Electrosurgical Electrode, Monopolar, Reusable with accessories	Deferred for provision of following: - • Clarification/justification of the Family/system of the applied product under the MDR 2017 with documented evidence like catalogue/ brochure.

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				<ul style="list-style-type: none"> • Clarify the codes and names present in the FSC. • Provide Notarised and valid LOA or clarify. • Provide Service life certificate.
42.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	M/s KARL STORZ SE & CO. KG, Dr.-Karl-Storz-StraBe 34 78532 Tuttlingen, Germany.	KARL STORZ HF SYSTEMS (HF INSTRUMENTS/ HF Cables , HF Electrodes with ACCESSORIES	<p>Deferred for provision of following: -</p> <ul style="list-style-type: none"> • Clarification/ justification of the Family/ system of the applied product under the MDR 2017 with documented evidence like catalogue/ brochure. • Clarify the codes and names present in the FSC. • Clarify the brand name as per FSC/ Brochure and reproduce in the Form7A. • Provide Notarised and valid LOA or clarify. • Provide valid FQA • Provide Service life certificate.
43.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	M/s KARL STORZ SE & CO. KG, Dr.-Karl-Storz-StraBe 34 78532 Tuttlingen, Germany.	KARL STORZ ROTATIP FORCEPS INSERT (Laparoscopic Grasping Forceps, Reusable)	<p>Deferred for provision of following:-</p> <ul style="list-style-type: none"> • Clarification/ justification of the Family/ system of the applied product under the MDR 2017 with documented evidence like catalogue/ brochure. • Clarify the codes and names present in the FSC. • Clarify the band name as per FSC/ Brochure and reproduce in the Form7A. • Provide Notarised and valid LOA or clarify. • Provide valid FQA.
44.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden,Plot No. 3, Block No. 3, MCHS, Shaheed-e-Millat Road, Karachi	Legal Manufacturer: M/s Grifols Diagnostic Solution INC, 4560 Horton Street, Emeryville,CA 94608,USA	<p>Procleix plasmodium assay kit (1000tests) (9052707</p> <p>Procleix plasmodium assay calibrators kit(15 sets)(9052709)</p> <p>Procleix plasmodium assay kit (5000tests) (9052708)</p> <p>Procleix plasmodium assay calibrators kit (75 sets)(9052710)</p>	<p>Deferred for submission of following:-</p> <ul style="list-style-type: none"> • Valid notarsied LOA since the submitted LOA is valid till October 2023. <p>Apply separately for the Procleix plasmodium assay kit(5000 tests) (9052708) & Procleix plasmodium assay kit(1000tests)(9052707) or clarify as kit/cluster under the MDR 2017.</p>

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45.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Plot No. 3, Block No. 3, MCHS, Shaheed-e-Millat Road, Karachi	Legal Manufacturer M/s Masimo Corporation, 52 discovery Irvine, California, USA, 92618	O3 SENSOR (3756),(4235) Regional oximeter and accessories	Deferred for submission of the following documents:- <ul style="list-style-type: none"> Valid and Notarised LOA for the product applied. Since the submitted LOA is expired. Clarify the name of the product as per FSC and reverse form 7A as per the brand name in the FSC and brochure.
46.	M/s H.M. Disposables, Office No. 24 & 25, Mezzanine Floor, Medicine Corner, Katchi Gali # 2, Marriot Road Karachi-	(LEGAL MANUFACTURER) M M/S. Demophorius ltd 196 Archbishop Makarios III Ave. 3030 Limassol, Cyprus, 357 25 749896	Demotek Intravenous Cannula Small Wings SIZES: G-14, 16, 18, 20, 22 & 24	Deferred for submission of following:- <ul style="list-style-type: none"> Stability studies Valid ISO 13485. Production quality assurance certificate since these are now expired.
47.	M/s H.M. Disposables, Office No. 24 & 25, Mezzanine Floor, Medicine Corner, Katchi Gali # 2, Marriot Road Karachi-	LEGAL MANUFACTURER) M/S. Demophorius ltd 196 Archbishop Makarios III Ave. 3030 Limassol, Cyprus, 357 25 749896	Demotek Hypodermic Needle	Deferred for submission of following documents:- <ul style="list-style-type: none"> Stability studies Submit valid and notarised LOA of the applied product since the LOA submitted don't have the name of the applied product or clarify. The name of the product is Sterile hypodermic single needle in FSC and code not mentioned in the FSC, clarify. Declaration of Conformity (DOC)
48.	M/s H.M. Disposables, Office No. 24 & 25, Mezzanine Floor, Medicine Corner, Katchi Gali # 2, Marriot Road Karachi-	LEGAL MANUFACTURER) M/S. Demophorius ltd 196 Archbishop Makarios III Ave. 3030 Limassol, Cyprus, 357 25 749896	Demotek Infusion Set	Deferred for submission of following:- <ul style="list-style-type: none"> Stability studies. Submit valid and notarised LOA of the applied product since the LOA submitted don't have the name of the applied product or clarify. DOC Submit valid ISO 13485, production quality assurance certificate since these are now expired.
49.	M/s Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi, Pakistan	M/s Zhejiang Kindly Medical Devices Co. Ltd, No. 758 5th Binhai Road, Binhai Industrial Park, Longwan Distrit 325025, Wenzhou, Zhejiang China	YMS disposable Infusion set with Burette	Deferred for submission of following documents: - <ul style="list-style-type: none"> Valid and FSC, ISO and FQA Valid and notarised LOA or clarify. Stability studies Differretial fee of Rs. 18500/-

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50.	M/s Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12 th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500.	Legal Manufacturer: M/s Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S, Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye	Sasan Medical Disposable Multi Perfusion Set	Deferred for submission of stability studies. Valid Production Quality Assurance / FQA certificate
51.	M/s Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12 th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500.	Legal Manufacturer: M/s Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S, Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye	Sasan Medical Disposable Blood Cardioplegia Set Adult	Deferred for submission of stability studies, valid production quality assurance/ FQA certificate
52.	M/s Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12 th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500.	Legal Manufacturer: M/s Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S, Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye	Sasan Medical Disposable Hemofiltration Set	Deferred for submission of stability studies.valid production quality assurance/ FQA certificate
53.	M/s K.S. Agencies, Office 210, 2 nd Floor, Business Arcade, Main University Road, Karachi	Legal Manufacteurer: Huaiyin Medical Instruments Company Limited Manufacturing site No.8 West Ming Yuan Road, 223003, Huaiyin, China	GLY-STEEL Stain-less steel non-absorbable surgical suture	Deferred for submission of the Clarification regarding the generic name /brand name in the LOA and in the FSC and FQA certificate. Since the applied name is not present in these documents. Clarify. Submit stability studies reflecting the shelf life.
54.	M/s K.S. Agencies, Office 210, 2 nd Floor, Business Arcade, Main University Road, Karachi	Legal Manufacteurer: Huaiyin Medical Instruments Company Limited Manufacturing site No.8 West Ming Yuan Road, 223003, Huaiyin, China	Glyceryl PGLA PGLA (Polyglycolide-Co-L-Lactide)90%:10%	Deferred for submission of the Clarification regarding the generic name /brand name in the LOA and in the FSC and FQA certificate. Since the applied name is not present in these documents; Clarify.
55.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi	Legal Manufacturer: M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw, In46582, USA Manufacturing Sites: M/s DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA. M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA.	Knee Stems	Deferred for clarification family/system and the brand name, codes as per FSC and applied in form 7A since the brand name applied is not reflected in the FSC; attested FSC having the name of applied products or clarify. Provide the catalogue or brochure of the product.

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		M/s Johnson & Johnson Medical (Depuy-Suzhou) Ltd., No. 299, Changyang street, Suzhou Industrial park, SUZHOU, Jiangsu, China 215126		
56.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi	Legal Manufacturer: M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw, IN 46582, USA Manufacturing Sites: M/s DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA. M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA.	Knee Accessories	Deferred for clarification family/system and the brand name, codes as per FSC and applied in form 7A. Since the brand name applied is not reflected in the FSC. Submit embassy attested FSC having the applied products or clarify Provide the catalogue/ brochure of the product.
57.	M/s Briogene Pvt Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi	Manufacturer: By ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hiz. San. ve Tic. A. S. Kaynarca Mah. Kadiri Sok. D. Blok Apt No. 10B Pendik/ Istanbul Turkey.	ODAK Blood Grouping OBG-lissdiluent OBGLISS-500	Deferred for clarification of the CE certificate for the applied product.
58.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I Chundrigar Road, Karachi.	Legal Manufacturer: Zimmer Trabecular Metal Technology inc. 10 Pomeroy Road, Parsippany, New Jersey 07054 USA.	Trabecular Metal Acetabular Revision System (Hip Implants, Trabecular Metal Acetabular Augment)	Deferred for clarification of the codes, name of the product in the FSC and applied in the Form 7A. or revise Form 7A as per FSC and Apply separately for Buttress and Restrictor.
59.	M/s Ali Gohar & Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi	Legal Manufacturer: Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.	Zimmer Dermatome Skin Grafting System (Dermatome Skin Grafting System)	Deferred for submission of the following:- The brand name need clarification as per FCS along with the codes and component. Names in the FSC is Dermatome host, dermatome auto clave case etc clarify or revise Form 7A as per FSC.
60.	M/s Ali Gohar & Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi	Legal Manufacturer: Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.	Zimmer A.T.S 2200TS Tourniquet System (Automatic tourniquet system)	Deferred for submission of The brand name clarification as per FSC along with the codes and component. Names in the FSC is tourniquet nasket, torniquet stand base etc so clarify or revise Form 7A as per FSC Submit Label of the product.
61.	M/s Ali Gohar & Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi	Legal Manufacturer: Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.	Zimmer Mesh Graft II Expansion System (Mesh Graft II Expansion System)	Deferred for submission of The brand name clarification as per FSC along with the codes and component. The brand name need clarification

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				as per FCS since along with the codes and component. Names in the FSC is tourniquet nasket, torniquet stand base etc Label of the product need to be provided.
62.	M/s Uniprom Healthcare L-151, 2 ND floor, Sehba Akhter Road, block 13-D Gulshan-e-Iqbal Karachi.	Legal Manufacturer: Amity international address: Libra house, west street , Worsbrough Dale, Barnsley, S70 5PG, UK	VIRUSOLVE+ EDS (Didecyldimethyl ammonium chloride)	Deferred for submission of the following:- <ul style="list-style-type: none"> • Provide embassy attested FSC. • Notarsied ISO 13485 with final opportunity. • Clarification of the name of the principle abroad, the name of the legal manufacture is Amity Limited in the LOA and in the FSC it is Amity International.
63.	M/s K.S. Agencies Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi	Legal manufacturer: Betatech Medikal Cihazler sanayi, Mumessillik, Ic ve, Dis, Tic, Ltd. Sti. Iki Telli Organize Sanayi Bolgesi, Ataturk Oto Sanayi Sitesi, 22 Sok Unal, Is Merkezi No. 9 / Basaksehir, Istra Nbul, Turkey	OXICEL suture (Oxidized Regenerated Cellulose Absorbable Hemostat)	Deferred for clarification of the brand name since in the FSC of Spain brand name is Oxicel Powder Absorbable Powder Hemostat and applied is OXICEL suture (Oxidized Regenerated Cellulose - Absorbable Hemostat). Clarify the brand name and types if any or revise Form 7A as per FSC
64.	M/s Endovision Enterprises, A-173, Block - 3, Gulistan-e-Jauhar, Karachi	M/s Changzhou New District Garson Medical Stent Apparatus Co., Ltd, No. 06, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China	Garson Flextent Biliary Stent System Non-Covered	Deferred with final opportunity for submission of the notarsied and valid CE certificate since the submitted CE certificate does not possess Biliary stent
65.	M/s Endovision Enterprises, A-173, Block - 3, Gulistan-e-Jauhar, Karachi	M/s Changzhou New District Garson Medical Stent Apparatus Co., Ltd, No. 06, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China	Garson Flextent Biliary Stent System Partially Covered	Deferred with final opportunity for submission of the notarsied and valid CE certificate since the submitted CE certificate does not possess Biliary stent

2. In the light of the decision of MDB in its 37th meeting wherein the Board decided that once the firm has submitted original, valid and notarized/Embassy attested documents at the time of submission of application for registration/enlistment and the same are expired during the processing of application, the firm shall only submit valid and original (where applicable) documents without notarization/Embassy attestation.

3. It is requested to furnish the requisite information/documents mentioned in last column against each within 30 days after uploading of this letter on official website of DRAP.


 (AYYAZ AHMAD)
 Additional Director (MDMC)/
 Secretary MDB