



No.F.4-6/2024-MD (M-69)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 4th September, 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 69th meeting held on 26th & 27th June, 2024 and 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 Sure Bio-Diagnostics & Pharmaceuticals Address of Importer EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi.	LEGAL MANUFACTURER) Dia.Pro Diagnostic Bioprobes S.r.l (Manufacturing site) Via Giosuè Carducci, n°27 – Sesto San Giovanni (Milan), Italy	Virology Elisa	Deferred for the provision of the following documents:- <ul style="list-style-type: none">Valid and notarized LOAValid copy of FSC, ISO-13485.Provide justification of class as per DOC
2.	M/s Sure Bio-Diagnostics & Pharmaceuticals Address of Importer EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi	(LEGAL MANUFACTURER) M/s Dia.Pro Diagnostic Bioprobes S.r.l (Manufacturing site) Via Giosuè Carducci, n°27 – Sesto San Giovanni (Milan), Italy	Bacteriology Elisa	Deferred for the provision of the following documents:- <ul style="list-style-type: none">Valid and notarized LOAValid copy of FSC, ISO-13485.Provide justification of class as per DOC
3.	M/s Zenith International Room # 104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U, Karachi,Pakistan	M/s Shenzhen Homed Medical Device Co. Ltd, 3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District,Shenzhen, China	Piston Compressor Nebulizer	Deferred for the provision of notarized LOA with date of expiry/validity as LOA is more than 5 years old , and firm is further advised to submit valid ISO 13485, FSC & FQA certificate.
4.	M/s RECH International, 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi.	M/s Changzhou Kanghui Medical Device Innovation Co., Ltd Complete Address: No.11, north Changjiang Road, xinbei zone, Changzhou 213022, Jiangsu, P.R. China	Bone Screw	Deferred for provision of following documents:- <ul style="list-style-type: none">Codes mentioned are from German FSc are different from Chinese Fsc.No stability claims in form-7A or shelf life data (Metallurgy data)LOA expiredLabels of applied codes not presentFirm was asked to

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				<p>segregate five type of screw applied however firm has clubbed them in family.</p> <ul style="list-style-type: none"> Firm was asked to provide codes on form-7 however no codes provided.
5.	M/s RECH International, 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi.	M/s Changzhou Kanghui Medical Device Innovation Co., Ltd Complete Address: No.11, north Changjiang Road, xinbei zone, Changzhou 213022, Jiangsu, P.R. China	Intramedullary nails (Neogen)	<p>Deferred for the provision of following documents:-</p> <ul style="list-style-type: none"> Codes mentioned on DOC, German FSc & Chinese Fsc are different. Codes mentioned are from German FSc. ISO 13485 original notarized not provided FQA original notarized not provided No stability claims in form-7A or shelf life data LOA expired. Labels of applied codes not present.
6.	M/s RECH International, 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi.	M/s Changzhou Kanghui Medical Device Innovation Co., Ltd Complete Address: No.11, north Changjiang Road, xinbei zone, Changzhou 213022, Jiangsu, P.R. China	BONE PLATE	<p>Deferred for the provision of following documents</p> <ul style="list-style-type: none"> Codes mentioned on DOC, German FSc & Chinese Fsc are different. No stability claims in form-7A or shelf life data LOA expired Labels of applied codes not present Firm was asked to provide codes on form-7 however no codes provided.
7.	M/s Shams Enterprises Address of Importer Shop no 10 medicine market katchi gali no 1 north napier road karachi	LEGAL MANUFACTURER Anhui Easyway Medical Supplies Co., Ltd. (Manufacturing site) No.8 Tian Feng Road, Yongfeng Industry Area, Tianchang City, 239300 Anhui, China	A1 SURGICS STERILE SYRINGES	<p>Deferred for the provision of following documents:-</p> <ul style="list-style-type: none"> FSC from China is not notarized and counter sign by Pakistan embassy The firm is advised to apply separately for 100ml size
8.	M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi	Legal Manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: i. Changzhou Kanghui Medical innovations Co Ltd, No.11 North	Bone Plates	<p>Deferred for provision of following:-</p> <ul style="list-style-type: none"> Shelf life data and metallurgy data Notarized copy of Free Sale Certificate of country of origin

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		Changjiang road Xinbei Zone, Changzhou, Jiangsu, China.		
9.	M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi	Legal Manufacturer: M/s Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: M/s Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.	Bone Screws	Deferred for provision of shelf life and metallurgy data, apply separately for non sterile bone screws
10.	M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi	Legal Manufacturer: M/s Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: M/s Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.	General Spine System	Deferred for provision of shelf life data. Apply sepeately for immobilization and stabilization of spinal segments
11.	M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09	Legal Manufacturer: M/s Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: M/s Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.	Lockable Intermedullary Nails	Deferred for provision of shelf life data.
12.	M/s Shams Scientific Traders, Address of Importer 22-Y-J Madina Town, Faisalabad	legal manufacturer M/s Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA.	Healgen (H. Pylori Ab Rapid Test Cassette (Feces)	Deferred for the provision of updated and notarized LOA

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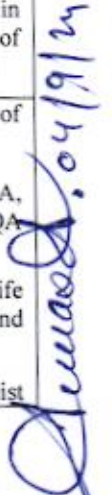
		Manufacturing site: M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China.		
13.	M/s The Cure, 1st Floor, Office 6, Capri Center, Firdous Market, Gulberg III, Lahore	M/s Dongguan TT Medical, Inc. Building No. 1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, PR China 523808	EverFlow (Paclitaxel Coated Balloon Catheter)	Deferred for the provision of original and attested FSC mentioning the applied device, since the applied device is not mentioned in the submitted FSC of Netherland
14.	M/s Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore.	Legal Manufacturer M/s Livetec Ingenieurburo Marie-Curie-Strasse 8 79539 Lorrach, Germany.	Pace T10 External Cardiac Pacemaker	Deferred for provision of shelf life studies. Further more the MDB decided to call for personal hearing to both the firms i.e M/S Novatek Pakistan and M/s Radiant Medical Lahore for clarification about the valid Letter of Authorization about the said product.
15.	M/s Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore.	Legal Manufacturer M/s Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany Manufacturing Facility: medPhoton GmbH KarolingerstaBe 16, 5020 Salzburg, Austria	ImagingRing m-Loop-X Mobile Imaging Robot (ImagingRing m)	Deferred for the provision of original and attested FSC mentioning the subject device.
16.	M/s Mian Scientific Corporation (Pvt) Limited, 534-Jinnah Colony Faisalabad	Legal Manufacturer M/s Shenzhen Tisenc Medical Devices Co., Ltd, 11F, 11G, Kechuang Building, Quanzhi Science and Innovation Park, Maozhoushan Industrial Park, Shajing Community, BaoAn District, Shenzhen, 518104, P.R, China	Tisenc B-Type Natriuretic Peptide (BNP) Kit	Deferred for the provision of following:- <ul style="list-style-type: none"> Differential fee of Rs. 25,000/- to be provided since Class-C product. Updated ISO 1385 Apply separately for other devices.
17.	M/s Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan.	Legal Manufacturer Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Contempo Rough Rider (Natural Rubber Latex Male Condoms)	Deferred for the provision of original documents.

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18.	M/s Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan.	legal manufacturer M/s Suretex Limited 31/1 Moo 4, Suratthani- Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Contempo Endurance (Natural Rubber Latex Male Condoms with Benzocaine)	Deferred for the provision of original documents.
19.	M/s Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan.	Legal Manufacturer M/a Suretex Limited 31/1 Moo 4, Suratthani- Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Skyn Original (Synthetic Polyisoprene Condoms)	Deferred for the provision of original documents.
20.	M/s Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan.	Legal Manufacturer M/a Suretex Limited 31/1 Moo 4, Suratthani- Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Skyn Intense Feel (Synthetic Polyisoprene Male Condoms)	Deferred for the provision of original documents.
21.	M/s Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan.	Legal Manufacturer M/s Suretex Limited 31/1 Moo 4, Suratthani- Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Contempo Wet n Wild (Natural Rubber Latex Male Condoms)	Deferred for the provision of original documents.
22.	M/s Lab Diagnostic Systems (SMC) Pvt Ltd, Plot No.36A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Legal Manufacturer M/s Pishro Tashkhis Fardavar (Manufacturing site) Pishro Tashkis Fardavar #1, Kavousi Street, south west Roudbar, Mirdamad Blvd. Tehran, Iran	Single Blood Bag	Deferred for provision of relevant valid FSC since the device is not mentioned in the submitted FSC of Iran.
23.	M/s Radiant Medical Private Limited 06-Sher Shah Block New Garden Town Lahore.	Legal Manufacturer M/s CARESTREAM HEALTH, Inc. 150 Verona Street, Rochester, New York USA 14608 Manufacturing site iRay Technology Taicang Ltd – No. 33 Xinggang Road- Taicang Port Economic and	Focus 35C Detector (digital Imaging System)	Deferred for the provision of original and updated Legal documents and apply separately for other type.

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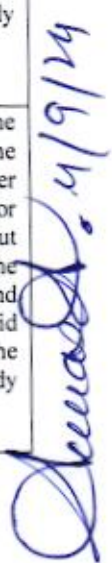
		Technological Development Zone – Taicang 215434 Jiangsu China		
24.	M/s Mian Scientific Corporation (PVT) Ltd, 534-Jinnah Colony Faisalabad.	Legal Manufacturer M/s CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.	Onsite (Typhoid IgG-IgM Rapid test kit)	Deferred for the provision of updated documents.
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 (H. pylori Ab Combo Rapid Test kit)	Deferred for the provision of updated documents.
26.	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.
27.	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 (Onsite Syphilis Ab Rapid Test Kit)	Deferred for the provision of updated documents and Apply separately for Onsite Syphilis Ab Combo Rapid Test Kit. The applied device falls in Class-C, so differential fee of Rs. 25,000 is to be provided.
28.	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 (AFP Fast Kit)	Deferred for the provision of updated documents and apply separately for SAA, PRL, PCT, NT-Pro-BNP, NGAL, HCG-Beta, D-Dimer, Cys, CEA, AMH, Vitamin-D-Fast Kits. The applied device falls in Class-C, so differential fee of Rs. 25, 000 is to be provided.
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 (CK-MB Fast Test Kit)	Deferred for the provision of updated documents and apply separately for CK-MB/cTnl Test Kit, tPSA, H-FABP kit, B2-MG kit, HBsAg Fast Test Kit. The applied device falls in Class-C, so differential fee of Rs. 25, 000 is to be provided.
30.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot	Legal Manufacturer M/s Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland	Romed (Foley Balloon Catheter)	Deferred for the provision of following: <ul style="list-style-type: none"> • Updated and notarized LOA, FSC, ISO 13485 and FQA certificates. • Product detail, Shelf life studies, manufacturing and QC details are missing. • Essential Principle checklist

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				<p>is missing.</p> <ul style="list-style-type: none"> • Labels of applied sizes, approved in the country of origin. • There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required. • Apply separately for 3-ways and Pediatrics.
31.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot	Legal Manufacturer M/s Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland	Romed (Endotracheal tubes, cuffed)	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Updated and notarized LOA, FSC, ISO 13485 and FQA certificates. • Product detail, Shelf life studies, manufacturing and QC details are missing. • Essential Principle checklist is missing. • Labels of applied sizes, approved in the country of origin. • There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required. • Apply separately for Uncuffed type.
32.	M/s Princess Scientific Services, Plot No.67/62, Adam-Jee Road IST Floor, Deen Plaza Saddar, Cantonment, Rawalpindi,	M/s Helena Biosciences Europe Queensway South, Team Valley Trading Estate, Gateshead, Tyne and Wear, NE11 0SD, UK	Helena Biosciences Europe Product Description: (The Epinephrine kit is intended for use in platelet aggregation studies.)	<p>Deferred for provision of differential fee of Rs. 20000/- as the product falls in class B, updated ISO certificate & stability studies as per Shelf life. Furthermore, the firm is required to clarify the Brand Name on the name of firm i.e. Helena Biosciences Europe.</p>
33.	M/s Princess Scientific Services, Plot No.67/62, Adam-Jee Road IST Floor, Deen	M/s Helena Biosciences Europe Queensway South, Team Valley Trading	Helena Biosciences Europe Product Description:	<p>Deferred for provision of differential fee of Rs. 20000/- as the product falls in class B, updated ISO certificate &</p>

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	Plaza Saddar, Cantonment, Rawalpindi,	Estate, Gateshead, Tyne and Wear, NE11 0SD, UK	(The Clauss Fibrinogen (Thrombin only) kit is intended for carrying out clot based haemostasis assays.)	stability studies as per Shelf life. Furthermore, the firm is required to clarify the Brand Name on the name of firm i.e. Helena Biosciences Europe.
34.	M/s Princess Scientific Services, Plot No.67/62, Adam-Jee Road IST Floor, Deen Plaza Saddar, Cantonment, Rawalpindi,	M/s Helena M/s Biosciences Europe Queensway South, Team Valley Trading Estate, Gateshead, Tyne and Wear, NE11 0SD, UK	Helena Biosciences Europe Product Description: (The Thrombin Time kit is intended for carrying out clot based haemostasis assays.)	Deferred for provision of differential fee of Rs. 20000/- as the product falls in class B, updated ISO certificate & stability studies as per Shelf life. Furthermore, the firm is required to clarify the Brand Name on the name of firm i.e. Helena Biosciences Europe.
35.	M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	Legal Manufacturer M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA Manufacturing site Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Vysis CEP Y (DYZ1) SpectrumAqua Probe	Deferred for clarification of the status of the product in the country of origin and under MDR 2017 whether it is IVD or otherwise and also clarify about the class applied here in. The firm shall submit Valid and embassy attested FSC.
36.	M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	Legal Manufacturer M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA Manufacturing site Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Vysis CEP 15 (D15Z4) SpectrumOrange Probe	Deferred for clarification of the status of the product in the country of origin and under MDR 2017 whether it is IVD or otherwise and also clarify about the class applied here in. the firm shall submit Valid embassy attested FSC and valid ISO 13485 certificate in the country of origin if not already submitted and is still valid.
37.	M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	Legal Manufacturer M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA Manufacturing site Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Vysis IntelliFISH Hybridization Buffer 5*250ul	Deferred for clarification of the status of the product in the country of origin and under MDR 2017 whether it is IVD or otherwise and also clarify about the class applied here in. the firm shall submit valid ISO 13485 certificate in the country of origin if not already submitted.
38.	M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	Legal Manufacturer M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA (Manufacturing site) Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Vysis IntelliFISH Universal FFPE Tissue Pretreatment and Wash Reagents	Deferred for clarification of the status of the product in the country of origin and under MDR 2017 whether it is IVD or otherwise and also clarify about the class applied here in. the firm shall submit Valid and embassy attested FSC and valid ISO 13485 certificate in the country of origin if not already submitted.



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39.	M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	Legal Manufacturer M/s Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA Manufacturing site Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Vysis CEP X (DXZ1) SpectrumGreen Probe	Deferred for clarification of the status of the product in the country of origin and under MDR 2017 whether it is IVD or otherwise and also clarify about the class applied here in. the firm is shall submit Valid and embassy attested FSC and valid ISO 13485 certificate in the country of origin if not already submitted.
40.	M/s Advance Cardiology System, 316-317, 3 rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi	Legal Manufacturer M/s BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China	POT PTCA Balloon Dilatation Catheter	Deferred for clarification of stability studies and provide the conclusion of the Stability studies.
41.	M/s Advance Cardiology System, 316-317, 3 rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi	Legal Manufacturer M/s BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China	Alveo HP Balloon Dilatation Cather	Deferred for clarification of the stability studies and provide the conclusion of the Stability studies. Submit valid and notarized FSC along with valid FQA and Design Examination certificate.
42.	M/s Advance Cardiology System, 316-317, 3 rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi	Legal Manufacturer M/s BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China	Pronavi Microcatheter	Deferred for clarification of the stability studies and provide the conclusion of the Stability studies. Submit valid and notarized FSC along with valid FQA and Design Examination certificate.
43.	M/s ACP System, 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi	Legal Manufacturer M/s CardioTek B.V., Dr. Nolenslaan 107B 6136 GL Sittard, The Netherland	EP – TRACER 38	Deferred for submission of the following documents: <ul style="list-style-type: none">• Submit complete stability studies• Valid and notarized LOA• Valid and notarized FSC• Valid ISO 13485 and FQA
44.	Name M/S Briogene Pvt Ltd, 196-A, Sindhi, Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi	Legal Manufacturer M/s Qiagen GmbH, Qiagen Strasse 1, 40724, Helden, Germany Manufacturing site Veracyte SAS, 163, Avenue de Luminy, 13009, Marseille, France	IPSOGEN® BCR-ABL 1 MBCR IS-MMR DX Kit Cat # 670823 (24)	Deferred for submission of the following: - <ul style="list-style-type: none">• Valid and notarized LOA• Valid ISO 13485 of the plant in France

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45.	M/s K.S Agencies, Office No, 210, Business Arcade, Main University Road, Karachi 33 & 34 Business Arcade, Main University Road, Karachi	Legal Manufacturer M/s. Katsan Medical Devices, KATSAN KATGÜT SANAYİ VE TİCARET A.Ş AOSB 10041 Sokak No:22 Cigli, Izmir/ Turkey	Alcalene polypropylene Suture (Non-absorbable Suture)	Deferred for submission of the following: - <ul style="list-style-type: none">• Valid FQA• Submit embassy attested FSC having all the applied codes or clarify• Submit the outcome of the ongoing investigation regarding the visual defect as mentioned in the stability studies, relevant portion is reproduced as under: <i>"The above images show two samples from with (top) and without (bottom) yellowing. The tests carried out mainly with yellowing products and positive results indicate that yellowing may be the result of extreme physical effects during accelerated aging. Corrective preventive action was initiated within KATSAN DÓF 73 (EK06) and connected with the package manufacturer. An investigation is ongoing to reveal the causes of this visual defect."</i>
46.	M/s K.S Agencies, Office No, 210, Business Arcade, Main University Road, Karachi 33 & 34 Business Arcade, Main University Road, Karachi	Legal Manufacturer M/s. Katsan Medical Devices, KATSAN KATGÜT SANAYİ VE TİCARET A.Ş AOSB 10041 Sokak No:22 Cigli, Izmir/ Turkey	ALCALACTINE PGLA Suture (Absorbable Suture)	Deferred for submission of the following: - <ul style="list-style-type: none">• Valid FQA & Design Examination certificate• Submit embassy attested FSC having all the applied codes or clarify• Submit the outcome of the ongoing investigation regarding the visual defect as mentioned in the stability studies, relevant portion is reproduced as under: <i>"The above images show two samples from with (top) and without (bottom) yellowing. The tests carried out mainly with yellowing products and positive results indicate that yellowing may be the result of extreme physical effects during accelerated aging. Corrective preventive action was initiated within KATSAN DÓF 73 (EK06) and connected with the package manufacturer. An investigation is ongoing to reveal the causes of this visual defect."</i>

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47.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr-e-Faisal, Karachi	Legal Manufacturer M/S Marflow AG Soodstrasse 57, CH-8134 Adliswil, Zurich, Switzerland	Ureteral Catheter	Deferred for submission of the following:- <ul style="list-style-type: none"> • Fresh fee of RS 25000/- • Valid ISO 13485. • Valid FQA and • Valid and notarized FSC.
48.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr-e-Faisal, Karachi	Legal Manufacturer M/s Marflow AG Soodstrasse 57, CH-8134 Adliswil, Zurich, Switzerland	Ureteral Stent Family D J stent and Set	Deferred for submission of the following:- <ul style="list-style-type: none"> • Clarify the class of the product under the MDR 2017 and submit Fresh fee as per the class. • Clarify and justify the code applied under the MDR 2017. • Submit Valid ISO 13485 and FQA and valid and notarized FSC.
49.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr-e-Faisal, Karachi	Legal Manufacturer M/s Marflow AG Soodstrasse 57, CH-8134 Adliswil, Zurich, Switzerland	Guide wire Family	Deferred for submission of the following:- <ul style="list-style-type: none"> • Clarify the class of the product under the MDR 2017 and submit Fresh fee as per the class. • Clarify and justify the code / different types applied under the MDR 2017 • Submit Valid ISO 13485 and FQA and valid and notarized FSC.
50.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr-e-Faisal, Karachi	Legal Manufacturer M/s Phenox GmbH, Lise-Meitner-Allee 31, D-44801 Bochum, Germany	p48 MW (HPC) Flow Modulation Device	Deferred for submission of the following:- <ul style="list-style-type: none"> • Submit fee of RS 50000/- • Submit Valid ISO 13485 • Valid FQA • Design examination certificate.
51.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Myoglobin CLIA Kit Myo(CLIA)	Deferred for clarification from the firm regarding the codes not present in the FSC.
52.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Generic Name: Total PSA CLIA (Total Prostate specific Antigen PSA (CLIA)	Deferred for clarification from the firm regarding the codes not present in the FSC.
53.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan	Maccura Generic Name: Reagent kit: B-type	Deferred for clarification from the firm regarding the brand name in the FSC since it is not present in the FSC or submit

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	Area, Islamabad	Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	natriuretic peptide BNP (CLIA)Kit Controls: B-type natriuretic peptide BNP control	embassy attested valid FSC along with CE Certificate. Submit stability studies
54.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Chemiluminescence Immunoassay multianalytes Control Level 1,2	Deferred for clarification from the firm regarding the codes not present in the FSC
55.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Product Name: Squamous cell carcinoma CLIA Kit and Control	Deferred for clarification from the firm regarding the codes not present in the FSC. Provide embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard.
56.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Inflammation Control	Deferred for clarification from the firm regarding the codes not present in the FSC
57.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: D-Dimer Chemiluminescent Immunoassay	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin as the provided FSC states that <i>exportation of the product is not restricted and comply the relevant standard.</i>
58.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Herpes simplex virus-1 IgG Antibody Chemiluminescent Immunoassay Kit	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard.
59.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Generic Name: Calcitonin (CT) CLIA Kit	Deferred for clarification of the codes of the products applied which is not found in the FSC; revise Form 7A as per FSC or provide embassy attested valid FSC having codes.
60.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza,	Legal Manufacturer M/s Maccura Biotechnology Co.,	Brand Name: Maccura Product Name: Carcinoembryonic	Deferred for clarification of the codes of the products applied which is not found in the FSC

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	Jinnah Avenue, Blue Area, Islamabad	Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	antigen CEA (CLIA)	revise Form 7A as per FSC or provide embassy attested valid FSC having codes.
61.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Cancer Antigen CA 19-9 (CLIA)	Deferred for clarification of the codes of the products applied which is not found in the FSC; revise Form 7A as per FSC Or provide embassy attested valid FSC having codes.
62.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Neuron Specific Enolase (CLIA) reagent kit with Neuron Specific Enolase (CLIA) control	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard. Furthermore, the product applied is not identical with the FSC.
63.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Cardiac Markers Control Plus Level 1, level 2, level 3	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard.
64.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura AFP CLIA Alpha feto protein (CLIA)	Deferred for clarification of the codes of the products applied which is not found in the FSC revise Form 7A as per FSC or provide embassy attested valid FSC having codes.
65.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Herpes simplex virus-1 IgM Antibody Chemiluminescent Immunoassay Kit	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard. Submit complete stability studies
66.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: CANCER ANTIGEN CA 15-3 (CLIA)	Deferred for clarification of the codes of the products applied which is not found in the FSC revise Form 7A as per FSC Or provide embassy attested valid FSC having codes.

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67.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Product Name: Creatine Kinase MB (CLIA) Reagent Kit CK-MB(CLIA)	Deferred for clarification of the codes of the products applied which is not found in the FSC revise Form 7A as per FSC Or provide embassy attested valid FSC having codes.
68.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Herpes simplex virus-2 IgG Antibody Chemiluminescent Immunoassay Kit	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since the provided FSC states that exportation of the product is not restricted and comply the relevant standard
69.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Cardiac Marker Control Level 1, Level 2 Kit	Deferred for clarification of the codes of the products applied which is not found in the FSC revise Form 7A as per FSC Or provide embassy attested valid FSC having codes.
70.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: TOXO IgM Antibody Chemiluminescent Immunoassay Kit	Deferred for clarification of the brand name as in the FSC Toxo Igm is written and the applied name is Toxo Igm Antibody Chemiluminescent Immunoassay Kit or revise Form 7A as per FSC .
71.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Product Name: Anti-Treponema pallidum CLIA Kit and Anti-TP Control	Deferred for clarification of the codes of the products applied which is not found in the FSC revise Form 7A as per FSC or provide embassy attested valid FSC having codes.
72.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: HE4 human epididymalprotein 4 (HE4) reagent Kit and HE4 Control	Deferred for submission of embassy attested valid FSC which reflect that the product is on Free sale in the country of origin since one of the submitted FSC for HE4 Control states that exportation of the product is not restricted and comply the relevant standard. Furthermore, the name of the applied product is HE4 human epididymalprotein 4 (HE4) reagent Kit Which is not identical with the brand name given in the FSC HE4 Chemiluminescent immune Assay Kit. similalry the applied codes are also not present in the FSC. Clarify or revise Form7A as per FSC.

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73.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: Procalcitonin (CLIA) Kit	Deferred for clarification of the codes of the products applied which is not found in the FSC, furthermore, the name of the product in the FSC is not identical with the applied brand name clarify or revise Form 7A as per FSC or provide embassy attested valid FSC having codes and name.
74.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Brand Name: Maccura Product Name: TOXO IgG Antibody Chemiluminescent Immunoassay Kit	Deferred for clarification of the name of the product in the FSC is not identical with the applied brand name clarify or revise Form 7A as per FSC or provide embassy attested valid FSC having name. Submit complete stability studies
75.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer M/s Maccura Biotechnology Co., Ltd., 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, Peoples Republic of China.	Maccura Product Name: N-terminal pro brain natriuretic peptide (CLIA)(NT-proBNP)	Deferred for clarification of the codes of the products applied which is not found in the FSC, clarify or revise Form 7A as per FSC or provide embassy attested valid FSC having codes and name.
76.	M/s Moody Global Services, No 14, 2 nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Legal Manufacturer Sichuan Nigale Biotechnology Co., Ltd Manufacturing site Sichuan Nigale Biotechnology Co., Ltd located at No. 28 kuixing road, 641400, Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA	Nigale Disposable Plasma Apheresis Set	Deferred for clarification of the variants applied not found in the FSC, clarify <ul style="list-style-type: none"> • Disposable Plasma Apheresis Set P-1000T • Disposable Plasma Apheresis Set P-1000J • Disposable Plasma Apheresis Set P-4016 or revise Form 7A as per FSC or provide embassy attested valid FSC having variants. Submit stability studies.
77.	M/s Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	M/s Hangzhou Alltest Biotech Co.,Ltd 550, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China	Caretest HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma	Deferred for submission of embassy attested valid FSC which reflect that the above product complies with the relevant standard and the exportation of the product are not restricted. this does not reflect that the product is on free sale in the country of origin.
78.	M/s Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	M/s Hangzhou Alltest Biotech Co.,Ltd 550, Yinhai Street, Hangzhou Economic and	Caretest HCV Rapid Test Cassette (Whole Blood/Serum/Plasma	Deferred for submission of embassy attested valid FSC which reflect that the above product complies with the relevant standard and the

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		Technological Development Area, 310018 Hangzhou, China		exportation of the product are not restricted. this does not reflect that the product is on free sale in the country of origin.
79.	M/s Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	M/s Hangzhou Alltest Biotech Co.,Ltd 550, Yin Hai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China	Caretest Malaria P.f/Pv Rapid Test Cassette (Whole Blood)	Deferred for submission of embassy attested valid FSC which reflect that the above product complies with the relevant standard and the exportation of the product are not restricted. this does not reflect that the product is on free sale in the country of origin. Submit notarized and valid CE certificate
80.	M/s Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	M/s Hangzhou Alltest Biotech Co.,Ltd 550, Yin Hai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China	Caretest Typhoid Rapid Test Cassette (Serum/Plasma)	Deferred for submission of embassy attested valid FSC which reflect that the above product complies with the relevant standard and the exportation of the product are not restricted. this does not reflect that the product is on free sale in the country of origin. Submit notarized and valid CE certificate and DOC.
81.	M/s Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	M/s Hangzhou Alltest Biotech Co.,Ltd 550, Yin Hai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China	Caretest Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)	Deferred for submission of embassy attested valid FSC which reflect that the above product complies with the relevant standard and the exportation of the product are not restricted . this does not reflect that the product is on free sale in the country of origin. Submit notarized and valid CE certificate or clarify.
82.	M/s Interex Company, 195, Block # 7/8, 2nd Floor, KMCHS, Justice Inamullah Road, near Hill Park Karachi 74800	Legal Manufacturer M/s Balton Sp. Z O.O.ul. Nowy Swiat 7/14, 00-696 Warszawa, Poland	Valver valvuloplasty catheter	Deferred for submission of:- • Notarized and valid LOA • Valid ISO 13485, • Valid FQA. • Design examination certificate. • Stability studies and DOC and valid FSC.
83.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore.	Legal Manufacturer M/s Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany	Leoni plus (Ventilator) Model: Leoni plus HFO 0217004 (DoC)	The Board deferred the case for Legal opinion from Legal division upon the issue that Endorsement of fee submission has been done in 05-12- 2019, while due to delay of original documents provided by principle, the application was submitted on 07-12-2023 by the firm.

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84.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore.	Legal Manufacturer M/s Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany	Leon plus (Anesthesia workstation) Model: Leon plus 0200010	The Board deferred the case for Legal opinion from Legal division upon the issue that Endorsement of fee submission has been done in 05-12- 2019, while due to delay of original documents provided by principle, the application was submitted on 07-12-2023 by the firm.
85.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore.	Legal Manufacturer Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany	Lifetherm 2000 (Baby warming Bed) Model: Lifetherm 2000 0215500hul200	The Board deferred the case for Legal opinion from Legal division upon the issue that Endorsement of fee submission has been done in 05-12- 2019, while due to delay of original documents provided by principle, the application was submitted on 07-12-2023 by the firm.
86.	M/s V care International, 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi	Legal Manufacturer M/s YASEE Biomedical Inc. NO.9, Xiuyuan Rd, High-Tech Development Zone, Qingdao City, China.	BeneSense PLUS (Blood Glucose Meter System) Model: AC-305	Deferred for provision of LOA.
87.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi	M/s Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China	Venous Disposable Automatic Core Instrument [Biopsy Needle & Needle Set for Soft Tissue Disposable, all types (Manual, Automatic & Semi-Automatic) all sizes]	Deferred with final opportunity for provision of Notarized and valid ISO-13485 certificate.
88.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi	M/s Zhanjiang Star Enterprises Co., Ltd. No. 1, West Jinhua Road, Mazhang District, 524094 Zhanjiang, People's Republic of China.	Venous Tracheostomy Tubes for Single use Cuffed & Un-Cuffed Various sizes & Types	Deferred with final opportunity for provision of remaining fee Rs.25,000/- and revised Form-7A in class C as DOC shows the same.
89.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi	M/s Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China	Venous Disposable Coaxial Biopsy Needle	Deferred with final opportunity for provision of Notarized and valid ISO-13485 certificate.
90.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha	M/s Suzhou Leapmed Healthcare Corporation, Wuzhong Science	Venous Disposable Semi-Automatic Instrument Biopsy Needle &	Deferred with final opportunity for provision of Notarized and valid ISO-13485 certificate.

M/s Total Technologies Pvt. Ltd
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	Chamber, Marston Road, Karachi	Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China	Needle Set for Soft Tissue Disposable, all types (Manual, Automatic & Semi-Automatic) all sizes & sizes as per FSC	
91.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi	M/s Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China	Venous Disposable Puncture Needle	Deferred for final opportunity for provision of Notarized and valid ISO-13485 certificate.
92.	M/s Royal Medical, Office No. 26th, 3rd Floor United Trade Center, Plot # 5, Block 6, Gulshan-e-Iqbal	Manufacturer: M/s F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium	CR-Type Catheter (Radiofrequency thermocoagulation probes)	Deferred with final opportunity to provide FSC with changed address
93.	M/s Royal Medical, Office No. 26th, 3rd Floor United Trade Center, Plot # 5, Block 6, Gulshan-e-Iqbal Karachi	Manufacturer: M/s F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium	EVRF (Endo-Venous Radiofrequency) Thermocoagulator	Deferred with final opportunity to provide FSC with changed address.
94.	M/s Royal Medical, Office No. 26th, 3rd Floor United Trade Center, Plot # 5, Block 6, Gulshan-e-Iqbal Karachi	Manufacturer: M/s F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium	HPR45i (Radiofrequency thermocoagulation probe)	Deferred with final opportunity to provide FSC with changed address.
95.	Universal Enterprises 29 Block 3, Overseas Cooperative Housing Society, Stadium Road, Karachi.	Legal Manufacturer: M/s Genthem Medical LLC. Located at 12011 Mosteller Road Cincinnati Oh 45241 United State of America.	Hemotherm (Dual Reservoir Cooler/ Heater System)	Deferred for Personal Hearing to M/s Hospicare (Pvt) Ltd., Lahore and M/s Universal Enterprises as same product is registered on the name of M/S Hospicare.
96.	M/s Oasis Medical Systems, Bangalow No. A-86, block C, Gulshan-e- Jamal, Karachi.	Legal Manufacturer M/s UTAS Technologies S.R.O., 1, Stavtelska st., Bratislava, 83104, Slovakia	UTAS (Patient Monitor UM-300S)	Deferred for provision of Original, embassy attested FSC, notarized LOA, Credentials of manufacturer, ISO certificate & FQA certificate.
97.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	M/s Nanjing Shouliang-Med Technology Co. Ltd. China, Zhongshan Science Park D9 block, No. 9 Kechuang Avenue, Jiangbei new area,	Soliang Non-Sterile Electrosurgical Vessel Sealer/Divider	The Board noted that applied product is Soliang Non-Sterile Electrosurgical Vessel Sealer/Divider while in the provided FSC it has mentioned as STERILE vessel sealer/Divider, Electrosurgical Generator.

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		Nanjing city, Jiangsu, China		<p>Furthermore, the firm applied as system while codes applied is not identical with the codes mentioned in FSC. Therefore, the board deferred the case with final opportunity for the following:</p> <ul style="list-style-type: none"> • Free Sale Certificate wherein the applied product shall be mentioned or revise Form-7A including brand & sizes/model/codes as per the Free Sale Certificate. • Clarification is required whether all the applied products/codes can be classified as system as per MDR 2017.
98.	Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800.	<p>Legal Manufacturer M/s OPTIKON 2000 S.p.A, Via Del Casale Di Settebagni, 13 – 00138 Roma Italy</p> <p>Mfg Site: M.s OPTIKON 2000 S.p.A. Via Del Casale Di Settebagni, 13 – 00138 Roma Italy</p>	CRYOLINE "CRYO MACHINE "	Deferred for clarification and submission of stability studies / service life.
99.	Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800.	<p>Legal Manufacturer M/s PhysiOL Liege Science Park, Allee des Noisetiers 4, B-4031 Liege, Belgium</p> <p>Mfg Site: M/s PhysiOL, Liege Science Park, Allee des Noisetiers 4, B-4031 Liege, Belgium</p>	PODEYE Hydrophobic Acrylic lens	Deferred for submission of Fee Rs.50,000/- or clarify with evidence of fee submission.
100.	Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800	<p>Legal Manufacturer M/s PhysiOL Liege Science Park, Allee des Noisetiers 4, B-4031 Liege, Belgium</p> <p>Mfg Site: M/s PhysiOL, Liege Science Park, Allee des Noisetiers 4, B-4031 Liege, Belgium</p>	POD F FINEVISION Hydrophilic Acrylic lens Class: C Shelf life: 5 years	Deferred for submission of Fee Rs.50,000/- or clarify with evidence of fee submission.
101.	Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800	<p>Legal Manufacturer M/s PhysiOL Liege Science Park, Allee des Noisetiers 4, B-4031</p>	POD FT Fine vision toric Class: C Shelf life: 5 years	Deferred for submission of Fee Rs.50,000/- or clarify with evidence of fee submission.

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		Liege,Belgium Mfg Site: M/s PhysiOL, Liege Science Park,Allee des Noisetiers 4,B- 4031 Liege,Belgium		
102.	M/s Muller & Phipps Pakistan (Pvt) Limited Uzma Court, Main Clifton Road, Karachi.	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel, Switzerland Manufacturer: M/s PT PHC Indonesia, Bekasi 17520, Indonesia (For Glucose Meter), M/s HTL-Strefa S.A., Poland (For Lancets / Lancing Device)	Contour Plus Elite Blood Glucose Monitoring System Contour plus elite blood glucose meter 1 lancing device 5 microlet lancets (already registred MDIR 0002615) Class-C Shelf Life:- 05 years Date of submission:- 25-05-2021 Fee Submission: Rs. 50,000/- Code & Size: 90007779, (FSC) 90010203 (DOC) Storage Conditions: Store between 0°C to 30°C	Deferred for clarification and submission of sample of medical devices to be packed as a single set for presentation before the board.
103.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan-e- Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece.	Premisut Absorbable Surgical Sutures Premisut PGLAR with & without Needle	Deferred for submission of valid Design examination certificate and FQA.
104.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan-e- Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece.	Premisut Absorbable Surgical Sutures Premisut PGLA with & without Needle	Deferred for submission of valid Design examination certificate and FQA.
105.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan-e- Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece..	Premisut Absorbable Surgical Sutures Premisut Polypropylene with & without Needle	Deferred for submission of valid Design examination certificate and FQA. The FSC submitted has brand name Premisut Polypropylene non absorbable surgical suture while applied is absorbable surgical suture; clarify.
106.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan-e- Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece.	Premisut Absorbable Surgical Sutures Premisut PGAR with & without Needle	Deferred for submission of valid Design examination certificate and FQA

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107.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece..	Premisut Absorbable Surgical Sutures Premisut PDO with & without Needle	Deferred for submission of valid Design examination certificate and FQA.
108.	M/s Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi	Manufacturer: M/s Atlas Medical S.A.28C, Miaouli STR. 153 44 Gerakas Athens-Greece.	Premisut Non-Absorbable Surgical Sutures Premisut SILK with & without Needle	Deferred for submission of valid Design examination certificate and FQA.
109.	M/s Hooraa Pharma (pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. ELI: 00037	Legal Manufacturer Siemens Healthcare Diagnostics Products Limited Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom Manufacturing site: Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom	IMMULITE / IMMULITE 1000 CK- MB (Kit) Class C Code: LKMB1 / 10381016 Size: 100 Tests Shelf life: 12 Months	Deferred since copy of the FSC provided has the brand name Immulite 2000CK-MB and is not identical with the Applied Name. Therefore, the firm need to clarify.
110.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr- e-Faisal, Karachi	Manufacturer: Fortune Medical Instrument Corp. 6F, No. 29, Sec.2 Jhongheng E RD.. Danshuei District, New Taipei City, 251 Taiwan	FORTUNE Stomach Gastric, Chest Laryngeal Mask Tube	Deferred for submission of embassy attested FSC in the Country of origin and clarify that which product to be considered for this application and apply separately for others. Submit valid CE certificate and stability studies.
111.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr- e-Faisal, Karachi	Manufacturer: Fortune Medical Instrument Corp. 6F, No. 29, Sec.2 Jhongheng E RD.. Danshuei District, New Taipei City, 251 Taiwan	FORTUNE Urological Catheters (Family) + Silicone Suprapubic Catheter	Deferred for submission of embassy attested FSC in the Country of origin and clarify that which product to be considered for this application and apply separately for others. Submit valid Ce certificate and stability studies.
112.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr- e-Faisal, Karachi	Manufacturer: M/s Phenox GmbH, Meitner-Allee 31, D- 44801 Bochum, Germany	pHLO AC Aspiration Catheter Family Intravascular recanalization device. Code: PHLO-72-115, PHLO-72-125, PHLO- 72-135	Deferred for submission of embassy attested FSC in the Country of origin and clarify that which product to be considered for this application and apply separately for others. Submit valid Ce certificate and stability studies.
113.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr- e-Faisal, Karachi	Manufacturer: Ningbo Multi-Way Medical Co., Ltd No. 225, Haiguan N. Rd, Cixi City 315300, Zhejiang Province, P.R. China	MULTI-WAY Guidewires	Deferred for clarification of the Brand name as per FSC or revise Form7A as per FSC. Submit valid ISO 13485 and embassy attested FSC in the country of origin

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 [Signature]

2. In the light of decision of MDB in its 37th meeting wherein 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

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