No.F.4-3/2023-MD (M-55)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
*****

Islamabad the 8th March, 2023

Subject:- **ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT – DEFERRED CASES (SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF)**

The applications of following applicants were placed before Medical Device Board (MDB) in its 55th meeting held on 16st February, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
I	II	III	IV	V
1.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2751) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**Truprone** (Poliglecaprone (PGCL) Absorbable Suture) Class D Shelf Life: 3 Years Sizes as per FSC	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.
2.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2748) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**Truglactin-910** (PGLA (Polyglactin 910) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.

3.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2747) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**TruCryl Rapid** (Polyglycolic Acid Rapids (Absorbable Suture) Codes & Sizes: As per FSC Class-D Shelf Life: 5 years	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete. .
4.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**Trulene** (Polypropylene (Non-absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.
5.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2756) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**Trusilk** (Silk (Black Braided Non-absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.
6.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2754)	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China	**Trulon** Nylon (Non-Absorbable Suture) Codes & Sizes: As per FSC Class-C	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC: 2. Product is from a non-reference country and the applicant has not provided FSC of any reference

	Evaluator: AD-II	FSC: China Valid till: 09.04.2023	Shelf Life: 5 years	country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.
7.	**M/s Bajwa Sons,** 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2749) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	**Truxanon** (Polydioxanon (Absorbable Suture) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: 1. Applied product is not mentioned in the provided FSC. 2. Product is from a non-reference country and the applicant has not provided FSC of any reference country or CE Mark certificates or WHO Pre-qualification: 3. Provided stability studies data is incomplete.
8.	**M/s Iqbal and Company,** Alfalah Manzil Opp. National Police Foundation, Street#26, Sector, E-11/4, Islamabad, Pakistan ELI- 00117 (3124) **Evaluator:**AD-II	**Legal Manufacturer:** M/s Gambro Lundia AB, Magistratsvägen 16 SE-226 43 Lund, Sweden. **<u>Manufacturing Site:</u>** M/s Gambro Lundia AB, Via Modenese, 66, Medolla (MO) 41036, Italy FSC: Sweden Valid till: 25-05-2022	**CleanCart A** Disinfectant for Hemodialysis Machine Class-B Shelf Life: 2 years	**Deferred** for provision of following documents: 1. Valid FSC: 2. Original and valid Full Quality Assurance System Certificate, duly notarized in the country of origin.
9.	**M/s Iqbal and Company,** Alfalah Manzil Opp. National Police Foundation, Street#26, Sector, E-11/4, Islamabad, Pakistan ELI- 00117 (3156 **Evaluator:**AD-II	**Legal Manufacturer:** M/s Gambro Lundia AB, Magistratsvägen 16 SE-226 43 Lund, Sweden. **<u>Manufacturing Site:</u>** M/s Gambro Lundia AB, Via Modenese, 66, Medolla (MO) 41036, Italy FSC: Sweden Valid till: 25-05-2022	**CleanCart C** Disinfectant for Hemodialysis Machine Class-B Shelf Life: 2 years	**Deferred** for provision of following documents: 1. Valid FSC: 2. Original and valid Full Quality Assurance System Certificate, duly notarized in the country of origin.

10.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1155-C **Evaluator:**AD-II	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Endurity Core** **Pulse Generator** Class-D Shelf Life: 18 months	**Deferred** for rectification of following discrepancies: • Original & valid LOA, duly notarized in the country of origin: • Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: • Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): • Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: • Original and valid ISO 13485 Certificate, duly notarized in the country of origin: • Original & valid design examination certificate, duly notarized in the country of origin: • Credentials of manufacturer, duly notarized in the country of origin: • Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
11.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1156-C	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Endurity MRI** PULSE GENERATOR Class-D Shelf Life: 18 months	**Deferred** for rectification of following discrepancies: • Original & valid LOA, duly notarized in the country of origin: • Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed:

	Evaluator:AD-II			• Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): • Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: • Original and valid ISO 13485 Certificate, duly notarized in the country of origin: • Original & valid design examination certificate, duly notarized in the country of origin: • Credentials of manufacturer, duly notarized in the country of origin: • Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
12.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1157-C **Evaluator:**AD-II	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Assurity** Pulse Generator Class-D Shelf Life: 18 months	**Deferred** for rectification of following discrepancies: • Original & valid LOA, duly notarized in the country of origin: • Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: • Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong):

				• Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: • Original and valid ISO 13485 Certificate, duly notarized in the country of origin: • Original & valid design examination certificate, duly notarized in the country of origin: • Credentials of manufacturer, duly notarized in the country of origin: • Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
13.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1158-C **Evaluator:** AD-II	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Ellipse** Implantable Cardioverter Defibrillator Class-D Shelf Life: 2years	**Deferred** for rectification of following discrepancies: • Original & valid LOA, duly notarized in the country of origin: • Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: • Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): • Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: • Original and valid ISO 13485 Certificate, duly notarized in the country of origin: • Original & valid design examination certificate, duly notarized in the country of origin:

				• Credentials of manufacturer, duly notarized in the country of origin: • Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
14.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1159-C **Evaluator:**AD-II	**Legal Manufacturer:** M/s Abbott Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA FSC USFDA valid till 27-10-2023	**Fortify Assura DR** Implantable Cardioverter Defibrillator Class-D Shelf Life: 2years	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin: o Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin: o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
15.	M/s **Global Marketing Services** 111, Hali Road Westridge 1,	**Legal Manufacturer:** M/s Abbott Medical Cardiac Rhythm Management	**Quadra Assura** Cardiac Resynchronization	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin:

	Rawalpindi ELI-00109 1160-C **Evaluator:**AD-II	Division , 15900 Valley View Court, Sylmar, CA 91342, USA FSC USFDA valid till 27-10-2023	Therapy Defibrillator Class-D Shelf Life: 2years	o Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin: o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
16.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1161-C **Evaluator:**AD-II	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Quartet** Left Heart Leads Class-D Shelf Life: 3years	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin: o Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same

				product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin: o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
17.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1162-C **Evaluator:**AD-II	**Legal Manufacturer:** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Durata** Defibrillation Leads Class-D Shelf Life: 3years	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin: o Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin:

				o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
18.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109 1163-C **Evaluator:**AD-II	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942 FSC USFDA valid till 24-10-2024	**Tendrill STS** Defibrillation Leads Class-D Shelf Life: 3years	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin: o Original & valid termination agreement between legal manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin: o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
19.	M/s **Global Marketing Services** 111, Hali Road Westridge 1, Rawalpindi ELI-00109	**<u>Legal Manufacturer:</u>** M/s ST. Jude Medical CRM Division, 15900 Valley View ct. Sylmar. CA USA 91942	**Quadra Allure** Cardiac Resynchronization Therapy Pacemaker Class-D	**Deferred** for rectification of following discrepancies: o Original & valid LOA, duly notarized in the country of origin: o Original & valid termination agreement between legal

	1164-C **Evaluator:**AD-II	FSC USFDA valid till 24-10-2024	Shelf Life: 18 months	manufacturer and previous importer i.e M/s Physiomed: o Clarification is required regarding name and status of legal manufacturer since the applied medical device is already registered in the name of M/s Physiomed under authorization from M/s St. Jude USA whereas the firm has applied for registration of same product from M/s Abbott (Hong Kong): o Original & valid FSC, duly notarized and attested by Pakistan Embassy in the country of origin: o Original and valid ISO 13485 Certificate, duly notarized in the country of origin: o Original & valid design examination certificate, duly notarized in the country of origin: o Credentials of manufacturer, duly notarized in the country of origin: o Original Declaration of Conformity, to be printed on company letter head and duly signed and stamped.
20.	M/s Meritorious, Business Solution (Pvt) Ltd, Office No. 202, 2nd Floor, 153-D, Block-D, Civic Center, Phase-$,Bahria, Town, Islamabad. ELI: 00208 **Evaluator: AD-VIII** 1775 (P)	**Legal Manufacturer:** Hangzhou Proprium Biotech Co,. Ltd, 3F Building , 2 No. 755 Yinhai Road Hangzhou Econimic & Technological Development Area, Hangzhou, 310018 China. FSC: China Validity: 04.08.2021	Chitinase-3-Like Protein 1-CHI3L1 Test Kit (Colloidal Gold) Class-C Shelf Life: One year	**Deferred** for provision of following: 1. Valid & Original FSC of any RRA duly attested by the Embassy of Pakistan or CE marking certificate 2. Clarify that on the FSC of China manufacturer name Quzhou proprium Biotech Co,Ltd is written however this name is not present on Forn-7-A. 3. Also clarify that manufacturing license provided isuued to Hangzhou Proprium Biotech Co,. Ltd, China.
21.	M/s Meritorious Business Solutions (Pvt) Ltd., House No. 39, College Road, Safari	M/s AccuBioTech Co., Ltd Building 10, No. 28 Yuhua Road, Beijing 101300 China	ACCU-TELL ® HEV IgM Cassette Class D Shel life 12 months	**Deferred** for provision of embassy attested original & valid FSC in the country of origin china

	Villas 1, Bahria Town, Rawalpindi. **Evaluator:** AD-VII		Code ABT-IDT-B246	

2. In the light of decision of MDB in its 37th meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notarized/Embassy attested documents at the time of submission of application for registration/enlistment and is expired during the processing of applications, such firms shall only submit valid and original (where applicable) documents.

3. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.

08/03/2023

(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB