



No.F.4-8/2022-MD (M-52)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 19th December, 2022.

Subject:- **REGISTRATION/ENLISTMENT 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 52nd meeting held on 24th November, 2022 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. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC Original issued on 08-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands.	Starbalm Red Balm 10G 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.
2.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC Original issued on 08-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands	Starbalm Red Balm 25G 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.

Deferred Letters of 52nd Meeting of MDB (24-11-2022)

Page | 1

3.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC Original issued on 04-02-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands	Starbalm Massage Lotion 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.
4.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC Original issued on 08-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands	Starbalm Massage Oil 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.
5.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC Original issued on 26-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands	Starbalm Stick 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.
6.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC issued on 08-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands.	Starbalm White Balm 25G 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.

7.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103) Evaluator: AD-II	Legal Manufacturer Novum Pharma B.V. located at Keyersway 20 2201 CW Noordwijk, Netherlands FSC original issued on 08-03-2013 by CIBG Ministry of Public Health, Welfare and Sport, Netherlands	Starbalm White Balm 10G 3304.3090 Class A Shelf Life: 05 Years Fee submitted: Rs. 5,000/-	Deferred for further deliberation/ clarification.
8.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 3271-KP	Legal Manufacturer: Lake Regiion Medical Limited Butlersland, New Ross, Co Wesford Ireland Manufacturing Site: Brivant Limited Parkmore West Business Park Galway, Ireland FSC: U.S FDA Valid till: 12/06/2023	Victory TM 18 Polymer Tip Guidewire with Hydrophilic Coating (Guidewire for intravascular Interventional procedures) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for provision of following; i) Original attested and valid FSC ii) Original notarized Letter of Authorization. iii) Original ISO13485, FQA and design examination certificates. iv) Credentials of Legal manufacturer.
9.	M Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 3270-KP	Legal Manufacturer: Lake Regiion Medical Limited Butlersland, New Ross, Co Wesford Ireland Manufacturing Site: Brivant Limited Parkmore West Business Park Galway,	Victory TM 14 Polymer Tip Guidewire with Hydrophilic Coating (Guidewire for intravascular Interventional procedures) Class-D	Deferred for Provision of following; i) Original attested and valid FSC. ii) Original notarized Letter of Authorization iii) Original ISO 13485, FQA and design examination certificates. iv) Credentials of Legal manufacturer.
10.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra	Legal Manufacturer: M/s Dia.Pro Diagnostic Bioprobes S.r.l, Via Giosue Carducci, n 27- Sesto San, Giovanni (Milan), Italy.	Dengue virus IgG/IgM Elisa Class-C Shelf life: 15 Months	Deferred for provision of following; i) Differential fee of

	University Shaheed-e-Millat Express Way, Karachi. (ELI-00084)1913	FSC Italy Issuance Date 14-08-2018	Codes & Sizes as per FSC: DENG.CE DENM.CE	25,000/- as the applied device falls in Class-C whereas firm applied in Class-B. ii) Valid and original ISO13485. Apply separately for other devices.
11.	M/s Medzntech Pvt. Ltd.D-21, Sector 16-A. Govt. Teachers Co- operative Housing Society, KDA Scheme-33, Karachi. (ELI- 00657) Evaluator: AD-I -4432-	Manufacturer Alcon Laboratories Inc. 6201 South Freeway Fort Worth, Texas USA 76134 Mfg. Sites: Alcon Research LLC 15800 Alton Parkway, Irvine, CA 92618 Alcon Research LLC 9965 Buffalo Speedway Houston, TX 77054 Alcon Research LLC 714 Columbia Avenue Sinking Spring, PA 19608 FSC: USA, Date of Issuance: 23-09-2021 FSC valid till: 22-09-2023	LEGIONTM SYSTEM Cataract Lense Extraction Instrument Shelf Life: 2 years Class: C Codes & Sizes: As per FSC Rs.50,000/-	Deferred for provision of following documents; 1) Original and notarized Agency agreement or letter of authorization from manufacturer 2) Original Full QA Certificate of all the manufacturing sites 3) Original ISO 13485:2016 Certificate 4) ISO 13485 Certificate 5) Stability Studies of Legion System. 6) Declaration of Conformity
12.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator: AD-VI.	QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	QIAamp® DNA kit • Class -A • Shelf life: upto 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis

13.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator AD VI	Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	<ul style="list-style-type: none"> Master Mix Class -A Claimed Shelf life: upto 12 months 	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
14.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015)	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	SOLUTIONS Class -A Claimed Shelf life: upto 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
15.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD-VI	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	Tissue Lyser Class -A Claimed Shelf life: upto 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
16.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator AD-VI.	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	QIAamp® Accessory Set Class -A Claimed Shelf life: up-to 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis.

17.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator: AD VI	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	QIAamp® Buffer Class -A Claimed Shelf life: up-to 12 month	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR, 2017 with prescribed form; i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
18.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator: AD VI	Name of Manufacturer Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1.	PCR Kits Class -A Claimed Shelf life: 12 months	Deferred. The product is applied for 'RESEARCH USE Only' Firm is asked to apply as per rule 22(1) of MDR, 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
19.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator AD VI	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	INVESTIGATOR KIT Class -A Claimed Shelf life: up-to 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as per rule 22(1) of MDR 2017 with prescribed form i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis.
20.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-	Legal Manufacture QIAGEN GmbH, QIAGEN Strasse 1. FSC: N/A DATE OF FSC: N/A	RNA /DNA Kit Class -A Claimed Shelf life: up-to 12 months	Deferred. The product is applied for 'RESEARCH USE ONLY' Firm is asked to apply as

	Faisal, Karachi (ELI-00015) Evaluator AD VI			per rule 22(1) of MDR,2017 with prescribed form;i.e., Form-9 for the purpose of clinical investigation, examination, test or analysis
21.	Briogene (Pvt) Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator AD VI -3839-	Manufacture by: Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland FSC: FINLAND Issuance date of FSC:24- 02-2021.	Immunochemistry. (Cardiac Marker)	Deferred. <ul style="list-style-type: none"> Firm asked to provide valid CE Mark documents? Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers.
22.	Briogene (Pvt) Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator AD VI	Manufacture by: Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland FSC: FINLAND Issuance date of FSC:24- 02-2021.	Clinical Chemistry (Enzymes)	Deferred. Firm asked to provide valid CE Mark documents? <ul style="list-style-type: none"> Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers
23.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator AD VI	Manufacture by: Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland FSC: FINLAND Issuance date of FSC:24- 02-2021	Clinical Chemistry (Substrates) Codes as per FSC. Class -B	Deferred. <ul style="list-style-type: none"> Firm asked to provide valid CE Mark documents? Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers.
24.	Briogene Pvt Ltd., 196-A, Sindhi Muslim, Cooperative Housing	Manufacture by: Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland	Clinical Chemistry (Electrolyte)	Deferred. <ul style="list-style-type: none"> Firm asked to provide valid CE Mark documents?

	Society, Shahrah-e- Faisal, Karachi (ELI-00015) -3841-	FSC: FINLAND Issuance date of FSC: 24-02-2021.		Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers.
25.	Briogene Pvt Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) -4658-	Manufacture By ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hiz.San.ve Tic.A.S. Kaynarca Mah.Kadirli Sok.D.Blok Apt No.10B Pendik/Istanbul Turkey. FSC: Turkey (Istanbul) Issuance date of FSC: 04-01-2021. valid for 36 Months.	ODAK Blood Grouping OBG-liss diluent OBGLISS -500 • Codes as per FSC: • Class -B • Claimed Shelf life: 13 Months	Deferred. Firm asked to provide valid CE Mark documents?
26.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator AD-VI	Manufacture By ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hiz.San.ve Tic.A.S. Kaynarca Mah.Kadirli Sok.D.Blok Apt No.10B Pendik/Istanbul Turkey. FSC: Turkey (Istanbul) Issuance date of FSC: 04-01-2021. valid for 36 Months.	ODAK GEL CARD CENTRIFUGE ODAK Blood Grouping System OBGJKS-12, OBGJKS-24 • Codes as per FSC: • Class -A Claimed Shelf life:N/A	Deferred. • Firm asked to provide valid CE Mark documents? • Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers.
27.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator AD- VI	Manufacture By ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hiz.San.ve Tic.A.S. Kaynarca Mah.Kadirli Sok.D.Blok Apt No.10B Pendik/Istanbul Turkey. FSC: Turkey (Istanbul) Issuance date of FSC: 04-01-2021. valid for 36 Months.	ODAK GEL CARD (INCUBATOR) Codes as per FSC: Class -A Claimed Shelf life:N/A	Deferred. • Firm asked to provide valid CE Mark documents? Firm shall apply on separate application for other products that doesn't fall in the category of cardiac markers.

28.	PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi. (ELI-00055)2480	Legal Manufacturer: Philosys Co., Ltd., 28-5, Gwangwol-gil, Okgu-eup, Gunsan-si, Jeollabuk-do, 54172, Republic of Korea FSC Korea issuance: 04-02-2020	Evocheck M TM Blood Glucose Test Strip Class-C Shelf Life: 2 years Model: PS003	Deferred. Submit valid and original LOA and ISO 13485 and FSC Clarification required as Samrbrand name from other manufacturer applied by the same importer.
29.	Hakimsons (Pvt) Ltd Hakimsons House, A- 58/B, SITE Mangophir Road Karachi. ELI No. 00396 2619	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China. FSC China validity 26-07-2020	Foyomed Tracheostomy Tubes Class-B Shelf life: 5 years Codes & Sizes as per FSC	Deferred. Submit valid LOAFSC and ISO 13485 Verify as the address of manufacturer on label is differen from the rest of the documents.
30.	Hakimsons (Pvt) Ltd Hakimsons House, A- 58/B, SITE Mangophir Road Karachi. ELI No. 00396 2482	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China. FSC China validity 26-07-2020	Foyomed Suction Catheter Class-B Shelf life: 5 years Codes & Sizes as per FSC	Deferred. Submit valid LOAFSC and ISO 13485 Verify as the address of manufacturer on label is differen from the rest of the documents.
31.	Hakimsons (Pvt) Ltd Hakimsons House, A- 58/B, SITE Mangophir Road Karachi. ELI No. 00396 2620	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Devolpment Zone, 315145, Ningbo, China. FSC China validity 26-07-2020	Foyomed Endotracheal Tubes, Cuffed Class-B Shelf life: 5 years Codes & Sizes as per FSC	Deferred. Submit valid LOAFSC and ISO 13485 Verify as the address of manufacturer on label is differen from the rest of the documents.

32.	Hakimsons (Pvt) Ltd Hakimsons House, A- 58/B, SITE Mangophr Road Karachi. ELI No. 00396 2493	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Development Zone, 315145, Ningbo, China. FSC China validity 26-07-2020	Foyomed Burette Infusion set Class-B Shelf life: 5 years Codes & Sizes as per FSC: 150cc and 100cc	Deferred. Submit valid LOA FSC and ISO 13485 Verify as the address of manufacturer on label is different from the rest of the documents.
33.	Hakimsons (Pvt) Ltd Hakimsons House, A- 58/B, SITE Mangophr Road Karachi. ELI No. 00396 2483	Legal manufacturer: Ningbo MFLAB Medical Instruments Co. Ltd China No. 508 Yindong Road (N) Yinzhou Economic Development Zone, 315145, Ningbo, China. FSC China validity 26-07-2020	Foyomed Stomach Tube Class-B Shelf life: 5 years Codes & Sizes as per FSC:	Deferred. Submit valid LOA FSC and ISO 13485 Verify as the address of manufacturer on label is different from the rest of the documents.
34.	M/s The Biotech Scientific International, Office no. 2, 4 th floor Khyber II Plaza, G-15 Markaz, Islamabad [ELI: 00663] Evaluator AD-I	Legal Manufacturer: Acon Biotech (Hangzhou Linan) Co. Ltd. 1-5/F, Building 3, No. 33 Shidi Road, Qingshanhu Subdistrict, Linan District, Hangzhou Zhejiang, China. FSC (copy): China Date of issuance: 04-03-2021	FLOWFLEX SARS CoV-2 Antigen Rapid Test L031-129R5 Class-C Shelf Life: 2 years Codes & Sizes: As per FCS	Deferred. 1. The address on FCS is not the address as mentioned in Form-7A. 2. Original Agency agreement or letter of Authorization from manufacturer duly notarized by the country of origin. 3. Original Full QA Certificate of all the manufacturing sites. 4. Original ISO 13485 Certificate. 5. Declaration of Conformity 6. CE Certificate FCS from any RRA

35.	PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	Shenzhen Yimi Life Technology Co., Ltd., 305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, Shenzhen, 518118, China FSC: China Issuance date: 31.05.2022	Evocheck Pulse Oximeter (YM201) Class-C Shelf Life: 2 years Applied on the basis of CE marked document	Deferred. Submit valid and original LOA and ISO 13485 and FSC Clarification required as Samrbrand name from other manufacturer applied by the same importer
36.	PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	Microtech Medical (Hangzhou) Co., Ltd. No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang	Evocheck Go Blood Glucose Monitoring System Class-C	Deferred. Submit valid and original LOA and ISO 13485 and FSC Clarification required as Samrbrand name from other manufacturer applied by the same importer
37.	PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	Microtech Medical (Hangzhou) Co., Ltd. No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang P.R. China FSC: Netherland	Evocheck Go 50's Blood Glucose Test Strips Class-C Shelf Life: 2 years Applied on the basis of CE marked document	Deferred. Submit valid and original LOA and ISO 13485 and FSC Clarification required as Samrbrand name from other manufacturer applied by the same importer.
38.	M/s PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	Legal Manufacturer: Bionime Corporation No. 100, Sec 2, Daqing St., South Dist., Taichung City 40242, Taiwan FSC China Issuance Date 02-11-2021 ARTGA identifier 208442	Evocheck Blood Glucose Monitoring System Class-C Shelf Life: N/A Model: GM700S	Deferred. Submit valid and original LOA and ISO 13485 and FSC. Clarification required as Samr brand name from other manufacturer applied by the same importer

39.	PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	<u>Legal</u> <u>Manufacturer:</u> Bionime Corporation No.100, Sec 2, Daqing St., South Dist., Taichung City 40242, Taiwan FSC China Issuance Date 02-11-2021 ARTGA identifier 208442	Evocheck Blood Glucose Test Strip Class-C Shelf Life: 2 years Model: GS700	Deferred. Submit valid and original LOA, ISO13485 and FSC Clarification required as Samr brand name from other manufacturer applied by the same importer
-----	--	---	---	---

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.


(MUNEEZA KHAN)
 Additional Director (MDMC)/
 Tele: 051-9262183