



No.F.4-9/2022-MD (M-53)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 27th 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 53rd meeting held on 7th December, 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. Reliance Private Limited, 17/3-Maulana Zafar Ali Khan Road,Lahore ELI: 00158	Legal Manufacturer:SDI Limited, 3-15 Brunson StreetBayswater, Victoria 3153, Australia.	POLA (Dental etching agent) Codes & Sizes: Asper FSC Class-B Shelf Life: 27-months	Deferred for provision of ISO-13485 & FSCof RRA.
2.	M/s Humayun Dental Supplies, 43, Mozang Road,Lahore ELI: 00063. -2434-	Legal Manufacturer: M/sGC Corporation, 76-1, Hasunuma-Cho,Itabashi-Ku, Tokyo, 174-8585, Japan FSC: Japan(copy) Date of Issue: 9.07.2020	Elite Cement 100Asia 1-1PKG (Dental Zinc Phosphate Cement)Codes & Sizes: Asper FSC Class-B Shelf Life:36 months.	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.
3.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2435-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho,Itabashi-Ku, Tokyo, 174-8585, Japan FSC: Japan(copy) Date of Issue: 09.07.2020	EUGENOLEMENT (Dental Zinc OxideEugenol Cement) Codes& Sizes: AsperFSC Class-B Shelf Life:36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.

4.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2436-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho,Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site:GC Dental Products Corporation, 2- 285, Toriimatsu- cho, Kasugai-shi,Aichi, 486-0844, Japan. FSC: Japan (copy)	EVERX Posterior Dental composite resinsfor restoration Class-B Shelf Life: 02-years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies
5.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2437-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho,Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporation FujiOyama Factory, 584-1, Nakahinata,Oyama-Cho, Sunto-Gun, Shizuoka-Ken,410-1307 FSC: Japan (copy) Date of Issue: 09.07.2020	Fregenol Temporary Pack (Dental Zinc OxideNon- Eugenol Cement) Codes & Sizes:Asper FSC Class-B Shelf Life:36months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.
6.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2438-	Legal Manufacturer: M/sGC Corporation, 76-1, Hasunuma-Cho,Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporation Fuji Oyama Factory, 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307 FSC: Japan(copy) Date of Issue:	GC Fuji Bulk Universal (Dental Filling Glass Ployalkeonate Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: 26months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.

7.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore. ELI: 00063 -2439-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporation Fuji Oyama Factory, 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307 FSC: Japan Date of Issue: 09.07.2020	GC Fuji Plus (Dental resin-modified glass polyalkenoate luting Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
8.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -2440-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma-Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporation Fuji Oyama Factory, 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307 FSC: Japan (copy) Date of Issue: 09.07.2020	GC Gold Label Luting and Lining Cement (Dental Glass Polyalkenoate Luting Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
9.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -2441-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma-Cho, Itabashi-Ku, Tokyo, 174-8585, Japan. Manufacturing Site: GC Corporation Fuji Oyama Factory, 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307 FSC: Japan (copy) Date of Issue: 09.07.2020	GC Gold Label Universal Restorative (Dental filling Glass Polyalkenoate Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.

10.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2442-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan. Manufacturing Site: GC Corporation Fuji Oyama Factory, 584- 1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken,410-1307 FSC: Japan (copy) Date of Issue: 09.07.2020	GC Gold Label HSPosterior Extra (Dental FillingGlass Polyalkenoate Cement) Codes & Sizes: Asper FSC Class-B Shelf Life:24 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.
11.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2443-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan. Manufacturing Site: GC Corporation Fuji Oyama Factory, 584- 1, Nakahinata, Oyama-Cho, Sunto- Gun, Shizuoka-Ken, 410-1307 FSC: Japan (copy)Date of Issue: 09.07.2020	GC Gold Label IXExtra Capsule (Dental FillingGlass Polyalkenoate Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: 24months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.
12.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -2444-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan. Manufacturing Site: GC Corporation Fuji Oyama Factory, 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307 FSC: Japan (copy) Date of Issue: 09.07.2020	MI Varnish (Dental Cavity Varnish) Codes & Sizes: Asper FSC Class-B Shelf Life: 36months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.

13.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2445-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan. Manufacturing Site: 2.285 Toriimatsu-cho, Kasugai-shi, Aichi, 486-0844 Japan FSC: Japan(copy) Date of issue: 07.09.2020	SOLARE (Dental Composites resins for Restoration) Codes & Sizes: Asper FSC Class-B Shelf Life: 03-years.	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
14.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2446-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: 2.285 Toriimatsu-cho, Kasugai-shi, Aichi, 486-0844 Japan FSC: Japan Date of issue: 07.09.2020	G-AENIAL (Dental Composite Resins for Restoration) Codes & Sizes: Asper FSC Class-B Shelf Life: 36-months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
15.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2447-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporatin Fuji Oyama Factory 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka-Ken, 410-1307, Japan FSC: Japan Date of issue: 07.09.2020	G-CEM (Dental Resin-Modified Cement for Denture Reliner) Codes & Sizes: As per FSC Class-B Shelf Life: 24-months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
16.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku,	GC Gold Label LC (Dental filling Resin modified glass Polyalkeneate cement)	Deferred for provision of: a) LoA b) FSC

	ELI: 00063 -2448-	Tokyo, 174-8585, Japan Manufacturing Site: GC Corporatin Fuji Oyama Factory 584-1, Nakahinata, Oyama-Cho, Sunto-Gun, Shizuoka- Ken, 410-1307, Japan FSC: Japan Date of issue: 07.09.2020	Codes & Sizes: Asper FSC Class-B Shelf Life: 24 months	c) ISO-13485 d) Complete Stability Studies.
17.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -2449-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi- Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporatin Fuji Oyama Factory 584- 1, Nakahinata, Oyama- Cho, Sunto-Gun, Shizuoka-Ken, 410-1307, Japan. FSC: Japan Date of issue: 07.09.2020	MIRACLE Mix (Dental Core Build-up Glass Polyalkonate Cement) Codes & Sizes: Asper FSC Class-B Shelf Life: Not clear.	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
18.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -2450-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi- Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Corporatin Fuji Oyama Factory 584- 1, Nakahinata, Oyama- Cho, Sunto-Gun, Shizuoka-Ken, 410-1307, Japan FSC: Japan. Date of issue: 07.09.2020	SOFT-LINER 1-1PKG (Short Term softlining Materials for removable Denture) Codes & Sizes: Asper FSC Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.

19.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2451-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Dental Products Corporation 2- 285 Toriimatsu- cho, Kasugai-shi, Aichi, 486-0844 Japan FSC: Japan Date of issue: 07.09.2020	SOLARE Universal Bond (Dental dentin Adhesive) Codes & Sizes: Asper FSC Class-B Shelf Life: 24 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
20.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2442-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Dental Products Corporation 2- 285 Toriimatsu- cho, Kasugai-shi, Aichi, 486-0844 Japan FSC: Japan Date of issue: 07.09.2020	TEMPRON 1-1PKG (Dental Acrylic Resins for Crown and Bridge) Codes & Sizes: Asper FSC Class-B Shelf Life: 24 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
21.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063-2453-	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-8585, Japan GC Europe NV, Research Park Interleuvenlaan 22 B-3--1 Leuven, Belgium FSC: Belgium	EverStick (E-Glass Fibers and Lights Curable Resinous Matrix) Codes & Sizes: Asper FSC Class-B Shelf Life: 3 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
22.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma- Cho, Itabashi-Ku, Tokyo, 174-	REVOTEK LC (Dental Acrylic Resins for Crown and Bridge)	Deferred for provision of: a) LoA b) FSC

	ELI: 00063	8585, Japan. Manufacturing Site: GC Dental Products Corporation 2- 285 Toriimatsu- cho, Kasugai-shi, Aichi, 486- 0844, Japan FSC: Japan Date of issue: 07.09.2020	Codes & Sizes: Asper FSC Class-B Shelf Life: 24 months	c) ISO-13485 d) Complete Stability Studies.
23.	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 -4430-	Legal 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: US-FDA, Date of Issuance: 12-05-2020 FSC valid till: 11-05- 2022 FSC is expired since 11-05-2022	CENTURION® Vision System Small incision Cataract Lens Extraction Instrument Code: 8065751763	Deferred for provision of following: 1. Stability Studies of CENTURION Vision System Is not provided. 2. Original & valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. 3. Accessories codes missing as per provided FSC
24.	M/s Medzntech Pvt. Ltd. D-21, Sector 16-A. Govt. Teachers Co-operative Housing Society, KDA Scheme-33, Karachi. (ELI- 00657)	Legal Manufacturer Alcons Laboratorie Inc. 6201 South Freeway Fort Worth, Texas USA. 76134 Mfg. Sites: Alcon Grieshaber AG Winkelriedstrasse 52, 8302, Schaffhouse	ULTRAFLOW™ BIMANUAL I/A Disposable Handpiece Infusion/ Aspiration cannula Shelf Life: 3 years Class: B Products & Codes:	Deferred for the provision of following: 1. Original Declaration of Conformity not provided. 2. Stability Studies of ULTRAFLOW

	Evaluator: AD-I	Switzerland. FSC: Switzerland Date of Issuance: 25-09-2018 FSC valid till:24-09-2021 US-FDA, Date of Issuance: 20- 08-2021 FSC valid till: 19-08- 2023	As per FSC Fee challan 0588619778 (Rs.25,000/-)	IMANUAL I/A Disposable Handpiece not provided. 3. Complete description with intended use, Key functional elements, formulation & composition with unctionality is missing. 4. Validation studies not provided
25.	M/s Ro yal Medical, Office No. 26 th 3 rd Floor United Trader Center Plot No. 5, Block 6, Gulshan-e- iqbal, Karachi. (ELI-00691) Evaluator: AD-I -294-	Legal Manufacturer: Bicakcilar Tibbi Cihazlar Sayani ve.Tic A.S. OsmangaziMah. Gazi Cad. No. 21 Esenyurt 34522,Istambul, Turkey. FSC: Turkey Date of Issuance: 20-05- 2022, FSC valid till:19-05- 2025	BICAKCILAR Extracorporeal tubing set Shelf Life: 5 years Class: B Fee challan No. 8244652419 (Rs.25,000/-)	Deferred for provision of following: a) FCS of RRA asper rule 67 attested by embassy of Pakistan. b) Full Qualirty Assurance certificate/ Production QA certificate or equivalent, duly notarized by the country of origin. c) Original Declaration of Conformity
26.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063 -1623-P	Legal Manufacturing: Dr. Schumacher GmbH,Am Roggenfeld 3,34323 Malsfeld, Germany. FSC: Germany, Date of Issue: 17.06.2019	DESCOSEPT AF Alcoholic rapid disinfectant solution. Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
27.	M/s Humayun Dental Supplies, 43,Mozang Road, Lahore ELI: 00063 1620-P	Legal Manufactuing Dr. Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany FSC: GermanyDate of Issue: 17.06.2019	BIGUANID FLACHE-N Liquid concentrate for disinfection. Class-B Shelf Life: 24 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) CompleteStability Studies.

28.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -1621-P	Legal Manufacturing Dr. Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany FSC: Germany Date of Issue: 17.06.2019	DESCOSUC Disinfectant for dental suction systems Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
29.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 1622-P	Legal Manufacturing Dr. Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany FSC: Germany Date of Issue: 17.06.2019	Ultrason Active Powder concentrate for disinfection Class-B Shelf Life: 24 months.	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
30.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -1619-P	Legal Manufacturing Dr. Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany Dr. Schumacher Sp.zo.o ul. Boczna, 59-800 Luban, Poland. FSC: Germany, Date of Issue: 17.06.2019	DESSOCEPT-AF Wipes Alcoholic wipes for rapid disinfection Class-B Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
31.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063	Legal Manufacturing Dr. Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany Dr. Schumacher Sp.zo.o ul. Boczna, 59-800 Luban, Poland. FSC: Germany Date of Issue: 17.06.2019	Perfektan Extra (Pre-disinfectant cleaner for dental instruments) Class-C Shelf Life: 36 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
32.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemanstr.10, 41468 Neuss, Germany FSC: Germany Date of Issue: 05-03-2018	Meisinger Tungsten Carbide Instruments (Rotary Instruments for dental applications) Codes & Sizes: As per FSC Class-B Shelf Life: 10 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.

33.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemannstr.10, 41468 Neuss, Germany FSC: Germany Date of Issue: 05-03-2018	Meisinger Flexible Polishers(Rotary Instruments for dental applications) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
34.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemannstr.10, 41468 Neuss, Germany FSC: Germany Date of Issue: 05-03-2018	Meisinger Steel Instruments (Rotary Instruments for dental applications) Codes & Sizes:As per FSC Class-B Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
35.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemannstr.10, 41468 Neuss, Germany FSC: Germany Date of Issue: 05-03-2018	Meisinger Surgery Instruments (Rotary Instruments for dental applications) Codes & Sizes:As per FSC Class-B Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
36.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemannstr.10, 41468 Neuss, Germany FSC: Germany Date of Issue: 05-03-2018	Meisinger Ceramic Abrasives (Rotary Instruments for dental applications) Codes & Sizes: As per FSC Class-B Shelf Life: 10 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
37.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufacturer: M/s Hager & Meisinger GmbH Hansemannstr.10, 41468 Neuss, Germany FSC: Germany, Date of Issue: 05-03-2018	Diamond Instruments (Rotary Instruments for dental applications) Codes & Sizes:As per FSC Class-B Shelf Life: 10 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
38.	M/s Humayun Dental Supplies, 43,Mozang Road, Lahore	Legal Manufacturer: M/s Kuraray Noritak Dental Inc. 300 Higashiyama, Miyoshi-cho, Miyoshi, Aichi 470-0293, Japan	Cerabien ZR (Dental Porcelain) Class-B Shelf Life: 10 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability

	ELI: 00063	FSC: Japan, Date of Issue:11.04.2018		Studies.
39.	M/s Humayun Dental Supplies 43,Mozang Road Lahore ELI: 00063	Legal Manufacturer: M/s Kuraray Noritake Dental Inc. 300 Higashiyama, Miyoshi-cho, Miyoshi, Aichi 470-0293, Japan FSC: Japan Date of Issue: 11.04.2018	Noritake Super Porcelain Ex-3 (Dental Porcelain) Codes & Sizes: As per FSC: Class-B Shelf Life: 4years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
40.	M/s Humayun Dental Supplies, 43, Mozang Road,Lahore ELI:00063	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18-50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue:07/01/2021	KROMOGLASS (Dental cements) Codes & Sizes:As per FSC Class-B Shelf Life: 3 years	Deferred for provision of: a) LoA, b) FSC c) ISO-13485 d) Complete Stability Studies
41.	M/s Humayun Dental, 43, Mozang Road Lahore ELI:00063	Legal Manufacturer: M/s Medigma Biomedica GmbH SiemensstraBe, 10, 78564 Wehingen, Germany FSC: Germany Date of Issue:19/03/2021	MEDIGMA (Dental Drills Bone Cutting Instrument) Codes & Sizes:As per FSC Class-B Shelf Life: N/A	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
42.	M/s Humayun Dental, 43, Mozang Road Lahore ELI:00063	Legal Manufacturer:M/s Medigma Biomedica GmbH SiemensstraBe, 10, 78564 Wehingen, Germany Original FSC:Germany Date of Issue: 19/03/2021	MEDIGMA (Dental Implant& Abutments System) Codes & Sizes:As per FSC Class-C Shelf Life: 5years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
43.	M/s Humayun Dental Supplies, 43,Mozang Road,Lahore ELI: 00063	Legal Manufactuing Dr. Schumacher GmbH, Am Roggenfeld 3,34323 Malsfeld, Germany FSC: Germany Date of Issue:17.06.2019	Spezial Oispray (Spray for maintenance of instruments) Class-A	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability

	-345-P		Shelf Life: 7 years	Studies Further, clarification whether product falls under definition of MD as per MDR, 2017.
44.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063	Legal Manufacturer: M/s GC Corporation, 76-1, Hasunuma-Cho, Itabashi-Ku, Tokyo, 174-8585, Japan Manufacturing Site: GC Dental Products Corporation 2-285 Toriimatsu-cho, Kasugai-shi, Aichi, 486-0844, Japan. FSC: Japan Date of Issue: 07.09.2020	Fit Checker 1-1PKG White (Dental Fit Checking Material) Codes & Sizes: As per FSC Class-A Shelf Life: 24 months	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies
45.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 663-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue: 07/01/2021	KROMOPAN (Dental material for impression) Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies
46.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 664-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue: 07/01/2021	KROMOPANSIL (Dental material for impression) Codes & Sizes: As per FSC. Class-A Shelf Life: 4 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies
47.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI: 00063 -665-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue: 07/01/2021	IQ (Dental material for impression) Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.

48.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI:00063 -666-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy; Original FSC: Italy Date of Issue: 07/01/2021	SILAXIL (Dental material for impression) Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
49.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI:00063 -667-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue: 07/01/2021	MILIENIUM (Dental material for impression) Codes & Sizes: As per FSC, Class-A Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
50.	M/s Humayun Dental Supplies, 43, Mozang Road, Lahore ELI:00063 -668-P	Legal Manufacturer: M/s LASCOD Spa, Via L. Longo, 18- 50019 Sesto Fiorentino (FI), Italy Original FSC: Italy Date of Issue: 07/01/2021	Energyl (Dental material for impression) Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies
51.	M/s Humayun Dental, 43, Mozang Road Lahore ELI:00063	Legal Manufacturer: M/s Medigma Biomedica GmbH Siemensstr. 10, 78564 Wehingen, Germany FSC: Germany Date of Issue: 9/03/2021	Medigma (Dental Tools and accessories for implant System) Codes & Sizes: As per FSC Class-A Shelf Life: N/A	Deferred for provision of: a) LoA b) FSC c) ISO-13485 d) Complete Stability Studies.
52.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Changzhou Hualian Health Dressing Co., Ltd No. 55 Yuejin Road, Zouqu Town 213144, Zhonglou District Changzhou, Jiangsu China Fsc China Valid 27-07-2023	Safety Fine Ad Plaster. Codes & Sizes: As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data.

53.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Jinhua jingdi Medical Supplies Co., Building No.2, Ditian FunctionXiasohun Town, Jindong Zone, Jinhua City, Zhejiang China. FSC China issued on 24-07-2022	Safety Medical Tape (Non-Woven Paper Tape) Codes & Sizes:As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data
54.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Changzhou Hualian Health Dressing Co., Ltd No. 55 Yuejin Road, Zouqu Town 213144, Zhonglou District Changzhou, Jiangsu China Fsc China Valid 27-07-2023	Safety Fine Paper Tape. Codes & Sizes:As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data
55.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Changzhou Hualian Health Dressing Co., Ltd No. 55 Yuejin Road, Zouqu Town 213144, Zhonglou District Changzhou, Jiangsu China Fsc China Valid 27-07-2023	Safety Fine Non-Woven Dressing Roll. Codes & Sizes:As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data
56.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Huain Medicom Medical Technology Co., Ltd. No 123, Meicheng West Road, Qingpu Industry Park, Huanin City, Jiangsu, China Sterilization Site: M/s. Changzhou Medical & Health Suppliers Sterilization Co., Ltd. Heping Village	Star IV Catheter With Injection Port Plus HeparinCap Codes & Sizes:As per FSC Class-B Shelf Life: 05-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data

		Zhenglu Town, Wujin District 213114 Changzhou City China. FSC Germany issued on 10-05-2020		
57.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Jinhua Jingdi Medical Supplies Co., Ltd Building 2, Ditian Function, Xiaoshun Town, Jindong Zone, Jinhua City Zhejiang China. FSC China issued on 27-07-2022	Safety Medical Tape (Zinc Oxide Adhesive Tape) Codes & Sizes: As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data
58.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Jinhua Jingdi Medical Supplies Co., Ltd Building 2, Ditian Function, Xiaoshun Town, Jindong Zone, Jinhua City Zhejiang China. FSC China issued on 27-07-2022	Safety Medical Tape (Non- Woven Fabric Tape) Codes & Sizes: As per FSC Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data.
59.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Jinhua Jingdi Medical Supplies Co., Ltd Building 2, Ditian Function, Xiaoshun Town, Jindong Zone, Jinhua City Zhejiang China. FSC China issued on 27-07-2022	Safety Wound Dressing (Adhesive Wound Dressing) Codes & Sizes: As per FSC Class-A Shelf Life: 05-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485 d) Complete Stability Studies data
60.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi	M/s. Changzhou Hualian Health Dressing Co., Ltd No. 55 Yuejin Road, Zouqu Town 213144, Zhonglou District Changzhou, Jiangsu China. Fsc China Valid 27-07-	Safety Fine Wound Dressing (Adhesive Wound Dressing) Codes & Sizes: As per FSC. Class-A Shelf Life: 03-years	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin c) ISO-13485

	Eli-00293	2023		d) Complete Stability Studies data
61.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Jinhua Jingdi Medical Supplies Co., Ltd Building 2, Ditian Function, Xiaoshun Town, Jindong Zone, Jinhua City Zhejiang China. FSC China issued on 27-07-2022	Safety Cooling Gel Patch Codes & Sizes: As per FSC Class-B Shelf Life: Not mentioned	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin and any RRA c) ISO-13485 d) Complete Stability Studies data
62.	M/s. United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi Eli-00293	M/s. Huain Helan Medical instruments Co., Ltd. Group 3, Zhengtai Village, Matou Town, Huaiyin District, Huain City, Jiangsu China. FSC is not Provided.	Safety Disposable Surgical Blade Codes & Sizes: As per FSC Class-B Shelf Life: Not mentioned	Deferred for provision of: a) Original & valid Letter of Authorization; b) FSC of Country of origin and any RRA c) ISO-13485 d) Complete Stability Studies data
63.	Hakimsons (Pvt) Ltd, Hakimsons House, A-58/B, SITE Mangophr Road Karachi. ELI No. 00396 3260 Duplicate dossier	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 Reinforced Endotracheal tube, cuffed Class-B Shelf life: 5 years Codes & Sizes as per FSC	Deferred for provision of: a) Valid, notarized & original LOA, Production quality assurance certificate, FSC and ISO13485. b) Clarify since the address of manufacturer on label is different from the rest of the documents. c) Apply separately for uncuffed type
64.	M/s Royal Medical, Office No. 26 th 3 rd Floor United Trader Center Plot No.	Legal Manufacturer: Bicakcilar Tibbi Cihazlar Sayani ve Tic. A.S. Osmangazi Mah. Gazi Cad. No. 21	BEX-Cardioplegia Set Cardioplegia set	Deferred for the provision of followings: a) FCS of RRA as per rule 67 attested by

	5,Block 6, Gulshan-e- iqbal, Karachi. (ELI-00691) Evaluator: AD-I -293-	Esenyurt 34522, Istambul, Turkey. FSC: Turkey Date of Issuance:20- 05-2022 FSC valid till:19-05-2025	Shelf Life: 5 years Class: B Fee challan No. 32487500676 (Rs.25,000/-)	embassy of Pakistan is not provided. b) Full QA certificate/ Production QA certificate or equivalent, duly notarized by the country of origin is not provided. c) Original Declaration of Conformity.
65.	M/s Ferozsens Laboratories Limited, P.O Ferozsens, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Business & Technology Park, Model Farm Road Cork, Ireland FSC: USA Valid till: 20/06/2023	CRE Pulmonary Balloon Dilatation Catheter (Pulmonary Balloon Dilatation Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided • Submit differential fee of Rs.12,500/- since only Rs.12,500/- fee submitted.
66.	M/s Ferozsens Laboratories Limited, P.O Ferozsens, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC: USA Valid till: 22/02/2023	Coyote ES Over the Wire PTA Balloon Dilatation catheter (Peripheral angioplasty Balloon Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 37 Months	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided. Submit differential fee of Rs.12,500/- since only Rs.12,500/- fee submitted.

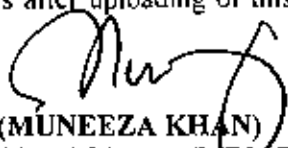
67.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC: USA Valid till: 22/02/2023	Coyote ES Monorail PTABalloon Dilatation Catheter (Peripheral angioplasty balloon catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 37months	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided. Submit differential fee of Rs.12,500/- since, only Rs.12,500/- fee submitted.
68.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC: USA Valid till: 22/02/2023	Coyote OvertheWire PTA Balloon Dilatation Catheter (Peripheral Angioplasty balloon catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 37months	Deferred for provision of following: a) Provide valid original and embassy attested FSC, since the firm has provided copy. b) Provide valid, original and notarized Letter of Authorization, since only copy is provided. c) Submit differential fee of Rs.12,500/- since only Rs.12,500/-
69.	M/s. Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC: USA, Valid till: 22/02/2023	Coyote Monorail PTA Balloon Dilatation Catheter (Peripheral angioplasty balloon catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 37 months	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided. • Submit differential fee of Rs.12,500/- since only Rs.12,500/- fee submitted.

				• Provide stability Studies
70.	M/s Ferozsos Laboratories Limited P.O Ferozsos, Amangarh, Nowshera (KPK) ELI-00120	Legal Manufacturer: M/s TOGO MEDIKIT CO., LTD 17148-6 AZA KAMEKAWA OAZA HICHIYA HYUGA CITY Miyazaki Japan, 883-0062 Manufacturing for: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA, USA FSC: USA Valid till: 20/10/2023	Super Sheath (Catheter Introducer and Interventional devices) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following: • Provide valid original ndembassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided. • Clarify whether the product is of M/s Togo Medikit Co or Boston scientific.
71.	M/s Ferozsos Laboratories Limited P.O Ferozsos, Amangarh, Nowshera (KPK) ELI-00120	Legal Manufacturer: M/s TOGO MEDIKIT CO., LTD 17148-6 AZA KAMEKAWA OAZA HICHIYA HYUGA CITY Miyazaki Japan, 883-0062 Manufacturing for: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA, USA FSC: USA Valid till: 20/10/2023	Super Sheath XL (Catheter Introducer and Interventional devices) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided • Clarify whether the product is of M/s Togo Medikit Co or Boston scientific.
72.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation 780	Expect™ Slimline Endoscopic Ultrasound Aspiration Needle (Needles) Codes & Sizes: As per FSC Class-B Shelf Life: 37 months	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original , and notarized letter of

		Brookside Drive, Spencer IN 47460, USA FSC: Ireland Valid till: 29/06/2023		Authorization, since only copy is provided • Fee not submitted, submit fee Rs.25,000/-.
73.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park, Galway, Ireland. FSC: Ireland Valid till: 29/01/2025	Mustang™ Over The Wire PTA Balloon Dilatation Catheter (Peripheral angioplasty balloon catheter, basic) Codes & Sizes: As per FSC Class-B Shelf Life: 37 months	Deferred for provision of following: • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorization, since only copy is provided • Submit differential fee of Rs.12,500/-. Since only 12500 fee submitted.
74.	M/s Bilal Enterprises, Commercial Complex Safari Villas-2 Bahria Town, Phase-7, Islamabad ELI: 00327 1599 (P)	Legal Manufacturer Endo Inventions LLC, 122 South Patterson Ave, Suite 206, 93111 Santa Barbara, California, US Odering Company Maillefer Instruments Holding Sarl, Chemin du, Verger- 3 CH-1338, Ballaigues, Switzerland FSC: California, US Valid Till: 11-06-22.	DENTSPLY Class-B Shelf Life:	Deferred for the following shortcomings: Clarify the brand name since the documents provided does not tally with the brand name.

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