



No.F.4-3/2024-MD (M-67)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 19<sup>th</sup> April 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 67<sup>th</sup> meeting held on 4<sup>th</sup> April, 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 Medilink Trading and Maintenance Private Limited, 654-D, Canal view, Lahore.  (ELI-00400) 1501-P 08-06-2020	<b><u>Legal Manufacturer:</u></b> SUMBOW MEDICAL INSTRUMENTS CO., LTD. 14F-01, No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China  FSC: China Date of Issue: 07-05- 2019 valid for 2 years	MEDILINK CANADA SURGICAL Disposable Pediatric Infusion Set with Burette. (150ml)  Class-B  Shelf Life : 5 years	<b>Deferred</b> for the provision of following: <ul style="list-style-type: none"><li>• Credentials of manufacturer abroad as per format approved in 3<sup>rd</sup> meeting by MDB.</li><li>• Original and valid FSC of country of origin and original agency agreement.</li><li>• The provided FSC of China is issued for Saudi Arabia and the Brand name mentioned on FSC is SUMBOW. Clarification is required.</li><li>• valid ISO-13485 certificate.</li><li>• The CE certificate provided us expired and missing the applied device.</li><li>• Technical information for manufacturing, QC and EPSPs as per Form-7A.</li><li>• Brand name includes 'CANADA', while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li><li>• Stability studies for the claimed shelf life.</li><li>• MRP of the device.</li></ul>
2.	M/s Medilink Trading and Maintenance Private Limited, 654-D, Canal view, Lahore.	<b><u>Legal Manufacturer:</u></b> SUMBOW MEDICAL INSTRUMENTS CO., LTD. 14F-01,	MEDILINK CANADA SURGICAL (Disposable Infusion Set)	<b>Deferred</b> for the provision of following: <ul style="list-style-type: none"><li>• Credentials of manufacturer abroad as per format approved in 3<sup>rd</sup> meeting by MDB.</li></ul>

	(ELI-00400) 1502-P 08-06-2020	No. 2 Building Shangdong Business Center, #1926 Canghai Road, Yinzhou, Ningbo 315041, China  FSC: China Date of Issue: 07-05- 2019 valid for 2 years	Class-B  Shelf Life : 5 years	<ul style="list-style-type: none"> <li>• Original and valid FSC of country of origin and original agency agreement.</li> <li>• The provided FSC of China is issued for Saudi Arabia and the Brand name mentioned on FSC is SUMBOW. Clarification is required.</li> <li>• Valid ISO-13485 certificate.</li> <li>• The CE certificate provided us expired and missing the applied device.</li> <li>• Technical information for manufacturing, QC and EPSPs as per Form-7A.</li> <li>• Brand name includes 'CANADA', while product is from CHINA. Brand name gives impression of claim of the products from CANADA, which needs to be rectified.</li> <li>• Stability studies for the claimed shelf life.</li> <li>• MRP of the device.</li> </ul>
3.	M/s Ahmad Care International, 2nd Floor, 7 Shahrah-e- Tajbagh, Main Market, Phase 1, Tajbagh Housing Scheme, Lahore, Pakistan.  ELI-00361 2735-P 17-09-2021	<b>Legal Manufacturer:</b> Shenzhen Antmed Co., Ltd, 18 Jinhui Avenue, Pingshan New District, Shenzhen 518122  FSC: China Valid till: 22.03.2023	Antmed (High Pressure Syringes)  Class-B  Shelf Life: 5 years	<b>Deferred</b> for the provision of original and updated /valid LOA, valid FSC and ISO 13485 certificate.
4.	M/s Ahmad Care International, 2nd Floor, 7 Shahrah-e- Tajbagh, Main Market, Phase 1, Tajbagh Housing Scheme, Lahore, Pakistan.  ELI-00361 2736-P 17-09-2021	<b>Legal Manufacturer:</b> Shenzhen Antmed Co., Ltd, 18 Jinhui Avenue, Pingshan New District, Shenzhen 518122  FSC: China (Master File) Valid till: 23.10.2021	ANTMED (Pressure Connecting Tube)  Class-B  Shelf Life: 5 years	<b>Deferred</b> for the provision of original and updated /valid LOA, valid FSC and ISO 13485 certificate.
5.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore  ELI: 00306 1625-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland	Dentsply Sirona (Gutta Percha Point for Protaper Universal series)  Class-B  Shelf Life: 4 years	<b>Deferred</b> for the provision of original and updated /valid documents including: <ul style="list-style-type: none"> <li>• LOA, FSC, ISO 13485 and FQA certificates.</li> <li>• QC tests and Stability studies.</li> </ul>

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		FSC: Switzerland valid till: 28 October, 2021	Codes as per FSC	Apply separately for others
6.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore ELI: 00306 1626-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland FSC: Switzerland valid till: 28 October, 2021	X-Smart (Endo Motor) Class-B Shelf Life: N/A Model: A 100400000000	<b>Deferred</b> for the provision of original and updated /valid documents including: • LOA, FSC, ISO 13485 and FQA certificates. • QC tests details. Apply separately for others
7.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore ELI: 00306 1627-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland FSC: Switzerland valid till: 28 October, 2021	ProGilder 3 files (Rotary Endodontic Files) Class-B Shelf Life: 5 years Codes: A092322100103 A092322500103	<b>Deferred</b> for the provision of original and updated /valid documents including: • LOA, FSC, ISO 13485 and FQA certificates. • QC tests and Stability studies. Apply separately for others
8.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore ELI: 00306 1628-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland FSC: Switzerland valid till: 28 October, 2021	Dentsply Sirona (Rotary Endodontic Files for Protaper Gold Series) Class-B Shelf Life: 5 years Codes as per FSC	<b>Deferred</b> for the provision of original and updated /valid documents including: • LOA, FSC, ISO 13485 and FQA certificates. • QC tests and Stability studies. Apply separately for others
9.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore ELI: 00306 1629-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland FSC: Switzerland valid till: 28 October, 2021	Unimetric (Root Canal Post) Class-B Shelf Life: N/A Codes as per FSC	<b>Deferred</b> for the provision of original and updated /valid documents including: • LOA, FSC, ISO 13485 and FQA certificates. • QC tests details. Apply separately for others
10.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore ELI: 00306 1630-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland	Diamond Bur (Burs) Class-B Shelf Life: N/A Codes as per FSC	<b>Deferred</b> for the provision of original and updated /valid documents including: • LOA, FSC, ISO 13485 and FQA certificates. • QC tests details.

*Handwritten signature and date:*  
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		FSC: Switzerland valid till: 28 October, 2021		
11.	M/s Mr. Dental Supply Pvt. Ltd UG-42, Land Mark Plaza Jail Road, Lahore  ELI: 00306 1631-P 19-08-2020	<b>Legal Manufacturer:</b> Maillefer Instruments Holding Sarl (Dentsply Sirona) Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland  FSC: Switzerland valid till: 28 October, 2021	Dentsply Sirona Paper Point (Paper Point for Protaper Universal series)  Class-B  Shelf Life: 4 years  Codes as per FSC	<b>Deferred</b> for the provision of original and updated/valid documents including:  • LOA, FSC, ISO 13485 and FQA certificates.  • QC tests and Stability studies.  Apply separately for others
12.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.  ELI: 00202 21-02-2024	<b>Legal Manufacturer:</b> Getting AB Lindholmospiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden  FSC Sweden Issuance: 17-04-2023 (Original)  LOA is valid till 13 <sup>th</sup> March 2024	Getinge aquadis 56 (Washer- disinfector)  Class-C  Shelf life: N/A  Codes: 56A 56M	<b>Deferred</b> for the provision of original and valid LOA.
13.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.  ELI: 00202 21-02-2024	<b>Legal Manufacturer:</b> Getting AB Lindholmospiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden  FSC Sweden Issuance: 17-04-2023 (Original)  LOA is valid till 13 <sup>th</sup> March 2024	Getinge 46 Series (Washer- disinfector)  Class-C  Shelf life: N/A  Codes: 46-4 46-5	<b>Deferred</b> for the provision of original and valid LOA.
14.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.  ELI: 00202 21-02-2024	<b>Legal Manufacturer:</b> <b>Legal Manufacturer:</b> Maquet GmbH Kehler Str. 31 76437 Rastatt Germany. <b>Manufacturing Site:</b> Maquet (Suzhou) Co., Ltd. No. 158 FangZhou Road, Suzhou Industrial Park, 215024 Suzhou, China.  FSC: Germany Date of issue: 15-03- 2023 (Original)  LOA is valid till 13 <sup>th</sup> March 2024	Getinge Solsus 66 series (Steam Sterilizer)  Class-C  Shelf life: N/A  Code: ST001-10 ST001-13 ST001-17 ST001-20	<b>Deferred</b> for the provision of original and valid LOA.


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15.	M/s Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore  ELI: 00045 2302-P 23-06-2021	<b>Legal Manufacturer:</b> Eagle Laboratories LLC, 10201-A Trademark Street, Rancho Cucamonga, CA 91730-589 U.S.A  FSC: USA valid till March 2021.	Eagle Gold Ophthalmic Knives (Ophthalmic Knives)  Class-B  Shelf Life: 5 years	<b>Deferred</b> for provision of original, valid and attested FSC, ISO 13485 and FQA.
16.	M/s MH Pharma Flat # 1118, 11th Floor, Eden Heights,6- Main Gulberg, Jail Road, Lahore  ELI: 00720 4586-P 24-01-2024	<b>Legal Manufacturer:</b> M/s Winner Guilin Latex Co., Ltd.No. 6 Wushan Road Guilin, China  FSC Original: China Valid till: 14/05/2025	GOBON (Male Latex Condom)  Class-C  Shelf Life: 5 years  Codes as per FSC	<b>Deferred</b> for further delibration regarding UNFPA Prequalification list provided by the firm.CE Mark / FSC reference country not provided
17.	M/s Contraceptives Pakistan (Pvt) Ltd, Office No.4A, Street No. 1, 116, Apartments Shah Jamal, Lahore  ELI:01178 4589-P 30-01-2024	<b>Legal Manufacturer:</b> M/s Guangzhou Double One, South Area of 3 # Rubber Road Chini Town, Huadu District, Gunagzhou City, Guangdong, Province, 510830 China  FSC Original: China Valid till: 04/06/2024	Double One (Natural Latex Male Condom)  Class-C  Shelf Life: 3 years  Codes/sizes: 49.0~55.0mm	<b>Deferred</b> for further delibration regarding UNFPA Prequalification list provided by the firm CE Mark / FSC reference country not provided
18.	M/s Shaheer Pharma Enterprises, Office No. 443/2, Bahadur Shah Zafar Link Road, Near Cheema Heart Centre, Sargodha  ELI: 00835 602-P 21-06-2021	<b>Legal Manufacturer:</b> Shandong Qiaopai Group Co., Ltd, economic zone of Gaoqing County, Zibo City 256300 Shandong Province People's Republic of China  FSC: China Valid till: 09.06.2022	Medivac (3-way stopcock)  Class-A  Shelf life: 5 years	<b>Deferred</b> for the provision of valid LOA, FSC, ISO 13485 and FQA/PQA certificate.
19.	M/s Ahmad Care International, 2nd Floor, 7 Shahrah-e- Tajbagh, Main Market, Phase 1, Tajbagh Housing Scheme, Lahore, Pakistan  -2734-	<b>Legal Manufacturer:</b> M/s Shenzhen Antmed Co., Ltd, 18 Jinhui Avenue, Pingshan New District, Shenzhen 518122.  FSC: China Valid till: 13.03.2022	ANTMED (Contrast Media Injectors)  Class-C  Shelf Life: 10 years  Codes as per FSC	<b>Deferred</b> with final opportunity for the provision of original and updated LOA.  The firm is advised to submit valid FSC and ISO 13485 certificate.

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2. In the light of decision of MDB in its 37<sup>th</sup> 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