

	M.A. ARAIN & BROTHERS (PVT) LTD.	
	EU DECLARATION OF CONFORMITY	Language : English
Document No. DOC-MDR-001 (Rev. 0)		Date: 31 MAY, 2021

EU DECLARATION OF CONFORMITY

M.A. Arain & Brothers (Pvt.) Ltd. hereby declares that;

Registered Address : Wazirabad Road, Sialkot-51310, Pakistan

Contact information : Tel: (+92) 52 4264926, 4264571, email : info@maarain.com

EUDAMED Registration (SRN #) : PK-MF-000012289

Appointed Authorized EU Representative for EU states

Name : Obelis s.a.

Company : Obelis s.a.

Registered Address: Bd. Général Wahis 53
1030 Brussels, BELGIUM

Contact information: Tel: + (32)2 732-59-54, Fax: + (32) 2 732-60-03, Email: mail@obelis.net

The EU declaration of conformity is issued under the sole responsibility of the manufacturer and tends to meet the essential and applicable requirements as per Annex IV under EU MDR 2017/745. Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of "Risk class I" of the device in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The products manufactured are provided in Annex A of this EC Declaration of conformity. The products declared in Annex A are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745. The traceability of the device covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System and UDI protocols, as well as its intended purpose.

We also declare;

Documents will be presented upon request by a competent authority, indicated therein, M.A. Arain & Brothers (Pvt.) Ltd will provide that technical documentation in its entirety and summary thereof.

The products manufactured are reusable - Class I (Non-Sterilized), lower risk products in line with Annex VIII;

The products referred to Annex A are developed with due care in lieu of technical documentation referred to in Annexes II and III.

To keep the technical documentation, the EU declaration of conformity and relevant certificates, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market.

The Basic UDI-DI as referred to in Part C of Annex VI had been established in reference to product in Annex A as per information to be submitted upon the registration of Devices and Economic Operators in accordance with articles 28, 29 and 31.

For and on behalf of M.A. Arain & Brothers (Pvt.) Ltd.



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Annex A

Product List

Declares that products list has been classified as Class I, as per the Rule mentioned respectively, is in conformity with the essential requirements and provisions of Medical Device Regulation 2017/745.

	<u>Article / Catalogue Ref #</u>	<u>Product Description</u>	<u>Class</u>	<u>Rule</u>	<u>UDI-DI</u>
1	42.0920.10	Spencer Ligature Scissors, 10.5 cm	Ir	6	+G127420920100%
2	49.0524.15	Billeau Currettes-Kurretten, 15.5 cm, Fig No.2	I	5	+G127490524150B
3	52.0354.02	Cusco Vaginal Specula, 100x25 mm	I	5	+G1275203540202
4	52.0334.01	Cusco Vaginal Specula, 75x17 mm	I	5	+G127520334010%
5	49.0559.02	Lucae Instrument Fig No.2, 3mm	I	5	+G127490559020F
6	52.0314.02	Grave Vaginal Specula, 95x35 mm	I	5	+G127520314020+
7	52.0346.03	Cusco Vaginal Specula, 100x35 mm	I	5	+G1275203460304
8	42.0110.13	Operating Scissors, 13 cm, Straight, Sharp/Blunt	Ir	6	+G127420110130-
9	42.0111.13	Operating Scissors, 13 cm, Curved, Sharp/Blunt	Ir	6	+G127420111130.
10	42.0379.14	Lister Bandage Scissors, 14 cm	I	I	+G127420379140B
11	43.0377.10	Baby-Mosquito Artery Forceps 10 cm, Curved	Ir	6	+G1274303771006
12	44.0380.16	Dressing Forceps 16 cm Straight, Serrated	I	4	+G1274403801607
13	44.0408.13	Tissue Forceps 13 cm Straight, 1x2 Teeth	Ir	6	+G1274404081305
14	49.0382.00	Hartmann Tuning Fork C1-256 Hz, without Silencers	I	I	+G1274903820007
15	49.0712.00	Only points for cartridge syringes	I	I	+G1274907120004
16	49.0717.04	Ear Syringe Complete, 100 ml	I	5	+G127490717040D
26	49.0718.00	Rubber Ring Set (For Ear Syringes)	I	5	+G127490718000A
17	41.0138.04	Scalpel Handle No. 4	I	1	+G127410138042
18	44.0130.12	Micro Adson dressing 12 cm	I	4	+G127440130120\$
19	43.0502.12	Halsted-Mosquito 12 cm str. 1x2 teeth	Ir	6	+G127430502120+
20	52.0310.01	Graves Vaginalspecula S 75x20mm	I	5	+G127520310010-
21	57.0490.00	Volkman Bone Curette 17cm Fig No.0	Ir	6	+G1275704900006
22	43.0600.14	Pean Artery Forceps 14 Cm Straight	Ir	6	+G127430600140%
23	52.0342.02	Vaginalspecula Cusco S/M	I	5	+G127520342020%
24	46.0808.09	Castroviejo Needle Holder 9cm	I	1	+G127460808090G
25	47.0168.26	BOZEMANN Polypus And Dressing Forceps, 26 Cm	I	4	+G127470168260F