

Ref: FI/DOCEU/004 May 25, 2021

EU DECLARATION OF CONFORMITY

Manufacturer:

FINI INSTRUMENTS

SURGICAL - DENTAL ELECTRO - BEAUTY CARE Near Rehman Academy, Kacha Shahab Pura Road, Sialkot-51310. Pakistan. S.R.N: PK-MF-000011898

Sr. No.	Article # / REF #	Description	Basic UDI
1	2001103	Dressing Forceps 14cm M/F	89640031922000011
2	2002210	Dressing Forceps 14cm S/F	
3	2002212	Thumb Dressing Forceps 11cm CVD.	
4	2002213	Thumb Dressing Forceps 11cm STR.	

Device Class: GMDN Code: Device Name: Intended Use:

Class I Rule 1 (Risk Classification of Annex VIII) 11791

Dressing Forceps

A hand-held manual instrument designed primarily for non-dedicated grasping of devices, sponges and/or dressings during a procedure; it is neither intended for tissue manipulation nor endoscopic use.

We hereby declared that the above-mentioned products meet all the essential general safety and performance requirements given in Annex I of MDR 2017/745 Article 19. All supporting documents are retained under the premises of the manufacturer.

The products manufactured are Class I (Non-Sterile, Non-Measuring and Non-Invasive), lower risk products in line with Annex VIII;

Applied Standards

EU MDR 2017/745, EN ISO 13485, ISO 9001, ISO 14971, ISO/TR 24971. ISO 15223-1, ISO 15223-2, ASTM A276-17.

EU Representative: **IBC-Sweden** 14550 Norsborg Stockholm, Sweden Email: eurep@ibcsweden.eu S.R.N: SE-AR-000001625







This Declaration of Conformity is valid until a revised Declaration of Conformity is issued.

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