

DECLARATION OF CONFORMITY EU

MANUFACTURER: MEDESYS srl

ADDRESS: viale dell'industria 1, I-33085 Maniago (PN), Italia

Hereby declares under its own responsibility that the below mentioned accessories for medical devices:

ENDODONTIC INSTRUMENTS

Generic name and codes: Enclosure 02

UDI-DI IDENTIFICATION: 805660060MEDFT01CHIGK

INTENDED USE: Endodontic instruments

Comply with the EU Regulation 2017/745 on medical devices.

They fulfill all the general safety and use requirements provided for in the annex I, annex II, annex III of the Regulation 745.

They are Class I medical devices according to the rule 1, annex VII of the Regulation 745.

They comply with the following harmonized regulation:

- UNI CEI EN ISO 14971:2020

Maniago, October 12th 2021

Diego GHEZZI (QM)


MEDESYS srl
MANIAGO Italy

Enclosure 02:

REF	DESCRIPTION
5550	Rubber dam punch
5551	Clamp forceps
5552	Rubber dam frame
5553	Rubber dam frame
5554	Rubber dam frame
5570	Clamp forceps
5580	Clamp forceps
5590	Clamp forceps
5605	Rubber dam clamp tray
5560/2	Rubber dam punch
5560/1	Rubber dam punch
2823	Clamp forceps
5595/XX	Clamps/assorted sizes
5610/XX	Rubber dam/assorted colors
981/XX	Cassette – assorted colors
1675/10	Dental dam kit
CK-585/MSY S	Retraction cord packer
585/XX	Retraction cord packer


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 MANIAGO - ITALY