



DECLARATION OF CONFORMITY

The Company Tecnofar s.p.a (Actor ID/SRN : IT-MF-000016099). with registered office located in Delebio (SO) – via della Battaglia, 17 – IT-23014,

DECLARES under its sole responsibility,

that it is the manufacturer of the medical device identified with Basic UDI-DI 805361077AGOGR , that is a sterile disposable needle for dental anaesthesia.

It complies with Regulation (EU) 2017/745 regarding medical devices, dated April 05, 2017 and with Directive 93/42/EEC for legacy devices¹. It is classified as a class IIa medical device, as per Annex VIII, Rule 6 of Regulation (UE) 2017/745 (Annex IX, Rule 6 of Directive 93/42/EEC).

- Dental needle is manufactured by Tecnofar according to standard*:
ISO 7885 - “Sterile, single-use dental injection needles”
 - The sterilisation complies with following standards*:
Ethylene oxide sterilization – UNI EN ISO 11135

Sterilisation of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

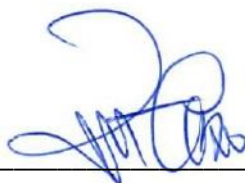
- The reference standards for Quality Management System are:
UNI EN ISO 9001:2015 and UNI CEI EN ISO 13485:2021
- the device is certified in compliance with Annex XI Part A of the Regulation (UE) 2017/745, with certificate n. 005-00-00-MDR issued by ITALCERT s.r.l. on 20/10/2022 (expire date 19/10/2027)

The present declaration applies to all the products listed in annex I.

* current edition

Delebio, 20/10/2022

Mr. Enzo Zappa/ Legal Representative _____



¹ Legacy devices should be understood as devices, which, in accordance with Article 120(3) of the MDR, are placed on the market after the MDR's date of application (DoA) and until 26 May 2024 if certain conditions are fulfilled.



Annex I – List of products

Size	Cannula diameter (mm)	Effective cannula length (mm)	Butt-end cannula length (mm)	Hub colour
30 G Short	0.30	25	11-13	yellow
30 G Short	0.30	21	11-13	yellow
30 G Extra short	0.30	16	11-13	yellow
30 G Extra short	0.30	12	11-13	yellow
27 G Long	0.40	36	11-13	grey
27 G Short	0.40	25	11-13	grey