TECNOFAR
QUALITY FIRST

Tecnofar SpA - 23020 Gordona (Sondrio) Italy Via al Piano, 54/A (zona Industriale)
Tel (+39) 0342 684115 (+39) 0343 48028 | **Fax** (+39) 0342 684500 (+39) 0343 41731
Sede legale Via della Battaglia, 17 23014 Delebio (SO) | **Web** www.tecnofar.it | **email** info@tecnofar.it
Cap. Soc. i.v. € 2.000.000,00 | **Reg. Imp.** SO 1391 | **R.E.A.** SO 27345 | **C.F. / P. IVA / Cod. CEE-IT**: 00080560147

SISTEMA DI GESTIONE CERTIFICATO
ITALCERT
UNI EN ISO 9001
UNI CEI EN ISO 13485

TUBI E MICROTUBI DI ACCIAIO INOSSIDABILE
AGHI DENTALI
MACCHINE PER ASSEMBLAGGIO AUTOMATICO

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.

It is classified as a class IIa medical device, as per Annex VIII, Rule 6 of Regulation (UE) 2017/745

- 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. 005-00-01-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, 18/02/2025

Mr. Enzo Zappa/ Legal Representative _____

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Annex I – List of products

BRAND NAME	NEEDLE SIZE	TECNOFAR ITEM CODE	PIERREL ITEM CODE	UDI-DI
ORABLOC	30G x 12 metric thread	V17480EO	103003012	08053610772029
ORABLOC	30G x 16 metric thread	V17481EO	103003016	08053610772036
ORABLOC	30G x 21 metric thread	V17482EO	103003021	08053610772050
ORABLOC	30G x 25 metric thread	V17483EO	103003025	08053610772067
ORABLOC	27G x 35 metric thread	V17484EO	102704035	08053610772081
ORABLOC	27G x 25 metric thread	V17485EO	102704025	08053610773552
ORABLOC	27G x 30 metric thread	V17486EO	102704030	08053610773569

GMDN code: 12740 – Needle, dental

A sterile, sharp bevel-edged, hollow tubular metal instrument with an integral hub, typically intended to be attached to a dental cartridge syringe for the injection of local anaesthetics. This is a single-use device