

EU DECLARATION OF CONFORMITY
MDR 2017/745

TITANOX S.r.l.

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Hereby declare under their own responsibility that

MEDICAL DEVICES CALLED
"DRY HEAT STERILIZING UNIT",

Subfamily	BASIC UDI-DI	Model	Code
Small	805930470A06SMALLA9	3I – 5I	A3-211-300 A3-212-400
Pasteur electric	805930470A06PASTELKU	20I – 60I – 120I	A3-213-400 A3-214-535 A3-215-670
Forced hot air	805930470A06VENTFORZZ4	20I – 60I – 120I	A3-213-400V A3-214-535V A3-215-670V
Pasteur electronic	805930470A06PASTELTNCMD	20I – 60I – 120I	A3-216-400 A3-217-535 A3-218-670

MANUFACTURED BY TITANOX S.R.L.,

**ARE COMPLIANT WITH THE GENERAL SAFETY AND PERFORMANCE
REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL DEVICES
REGULATION 2017/745.**

such medical device is complying with all the applicable requirements of the Medical Devices Regulation 2017/745, in particular:

- That the medical device above belongs to Class IIb, according to Annex VIII of the Medical Devices Regulation 2017/745, rule 16;
- That the medical device above HAS NO MEASURING FUNCTION;
- That the medical device above IS NOT TO BE USED FOR CLINICAL INVESTIGATION;
- That the medical device above IS NOT MARKETING IN A STERILIZED PACKAGE;
- That the conformity assessment process referred to in Annex IX of EU Regulation 2017/745 was followed by the Notified Body Kiwa Cermet Italia S.p.a. (Cadriano BO) (Certificate MDR 00011-A), n° 0476 and that the medical device above is manufactured according to the Quality System certified by the Notified Body 0476 Kiwa Cermet Italia S.p.a.

We certify that the devices also comply:

- with the requirements of Directive 2011/65 / EU and subsequent amendments, relating to the restriction of the use of certain hazardous substances in electrical and electronic equipment, implemented in Italy by Legislative Decree n.27 of March 4, 2014 and subsequent amendments
- with the requirements of Directive 2012/19 / EU and subsequent amendments of 4 July 2012 on waste electrical and electronic equipment (WEEE), as implemented in Italy by Legislative Decree No. 49 of 14 March 2014 and subsequent amendments

Torre de' Picenardi 27.06.2022

(place and date of issue)

Sole Administrator

Enrico Pisatti

(name and signature or stamping of the authorized person)