

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
"HEATER"

Intended purpose: Device intended to maintain stable thermal conditions of support materials and/or medical devices or physiological solutions.

Not intended for the heating or storage of blood products, body fluids, organs, parts of organs, or body tissues intended for reimplantation. Not intended for sterilization purposes.

BASIC UDI-DI: 805930470A11RISCZJ

Description	Code
Electronic Forced Air Heater 20l	A3-213-400/IV
Electronic Forced Air Heater 60l	A3-214-535/IV

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 I, according to Annex VIII of the Medical Devices Regulation 2017/745, rule 2;
- 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;

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
- with the requirements of Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment intended for use within certain voltage limits
- with the requirements of Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility

Torre de' Picenardi 20.11.2025

(place and date of issue)

TITANOX S.R.L.
26038 TORRE DE' PICENARDI (CR)
Sole Administrator
Enrico Gusatti
(name and signature or stamping of the authorized person)
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