

EU DECLARATION OF CONFORMITY
MDR 2017/745

TITANOX S.r.l.

Via Canove de' Biaffi - 26038 TORRE DE' PICENARDI (CR) - Tel: 0375394065
E-mail: info@titanox.it - SRN: IT-MF-000020325

Hereby declare under their own responsibility that

MEDICAL DEVICE

Code	Description
A4-POSEIDONE	BEDPAN WASHER "POSEIDONE"

Machine for washing and cleaning medical devices such as bedpans and urinals in plastic/stainless steel.

Basic UDI-DI: 805930470A08POSEIDP9

MANUFACTURED BY TITANOX S.R.L.,

IS COMPLIANT WITH THE ESSENTIAL 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:

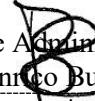
- That the medical device above belongs to Class I, according to Annex VIII of the Medical Devices Regulation 2017/745, rule 13;
- That the medical device above HAS NO MEASURING FUNCTION;
- That the medical device above IS NOT TO BE USED FOR CLINICAL INVESTIGATION;
- That the medical device above IS NOT MARKETED IN A STERILIZED PACKAGE;

We certify that the device 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 05.12.2022

(place and date of issue)


Sole Administrator
Enrico Busatti

(name and signature or stamping of the authorized person)