DELTA MED MEDICAL DEVICES
Solutions for Health
PART OF NUMANTEC HUMAN INNOVATION TECHNOLOGY

Via Guido Rossa, 20
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C. F. e P.IVA 01693020206

EU DECLARATION OF CONFORMITY
ACCORDING TO REGULATION MDR 745/2017, ARTICLE 19

MEDICAL DEVICE FAMILY:
FOLEY MANOMETER

Medical device Manufacturer identification.	
Name, registered trade name	DELTA MED SPA
SRN as referred to in Article 31	IT-MF-000027962
Registered office address	Via Guido Rossa N° 20, Viadana (MN), CAP 46019, Italy
Production site	Strada provinciale per Dubino N° 10, Delebio (SO), CAP 23014, Italy

This EU Declaration of Conformity is issued by Delta Med SpA under its full and sole responsibility, for all the medical devices listed in this document.

All the medical devices listed in this EU Declaration of Conformity are referred to the BASIC UDI-DI reported in the table enclosed with this declaration:

Basic UDI DI, reported in this Declaration of Conformity, is defined according to Part C of Annex VI of EU Regulation 745/2017.

This EU Declaration of Conformity covers all the medical devices listed in Table 1 enclosed with this document which are:

- Device medical device family group: **FOLEY MANOMETER**
- Intended purpose:

FOLEY MANOMETER is a sterile, disposable and non-invasive family of devices for monitoring intra-abdominal pressure ('IAP') through the bladder (bladder pressure or 'P-Vesical') in hospitalized patients (Accuracy: ± 5% of pressure reading).

The risk class of the devices was determined according to Rule 1, Main paragraph of Annex VIII-EU MDR 745/2017. FOLEY MANOMETERS are classified as a **Class Im** and **Class Is** medical devices.

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FOLEY MANOMETER in compliance with the following standards used and in relation to which conformity is declared:

- EN ISO 13485:2016+A11:2021 - Harmonized standard - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016).
- EN ISO 14971:2019+A11:2021 - Medical devices - Application of risk management to medical devices.
- IEC 62366:2015 - Medical devices – Part 1: Application of usability engineering to medical devices
- UNI EN 17141:2021 - Cleanrooms and associated controlled environments - Biocontamination control
- EN ISO 11607-1:2020+A11:2022 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- EN ISO 11607-2:2020+A11:2022 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- EN 556-1 Medical devices — Requirements for medical devices to be designated 'sterile' — Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11135:2014+A1:2019 - Sterilization of health care products – Ethylene Oxide- Part 1 – Requirements for development, validation and routine control of the sterilization process for medical devices.
- EN ISO 11737-1:2018 - Sterilization of health care products - Microbiological methods Determination of a population of microorganisms on products.
- EN ISO 11737-2:2020 - Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- EN ISO 11737-3:2023 - Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing.
- EN ISO 11138-1:2017 - Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017).
- EN ISO 11138-2:2017 - Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

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- EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- EN ISO 20417:2021 - Medical device. Information to be supplied by the manufacturer
- EN IEC 62366-1:2015 – Medical device. Part 1 – Application of usability engineering to medical device.
- EN ISO 14644-1:2015 - Clean rooms and associated controlled environments: classification of air cleanliness by particle concentration
- EN ISO 14644-2:2015 - Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance in terms of air cleanliness in terms of particle concentration
- EN ISO 14644-3:2019 - Cleanrooms and associated controlled environments - Part 3: Test methods
- EN ISO 14644-4:2022 - Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2022)
- European Guideline MEDDEV 2.12./1 - rev.8/2013 Guidelines on a medical device vigilance system
- EU Guideline MEDDEV 2.7./1 – rev.4/2016 Clinical Evaluation: A guide for Manufacturers and Notified Body.
- ASTM D4169 – Curr. Ed. Standard Practice for Performance Testing of Shipping Containers and Systems

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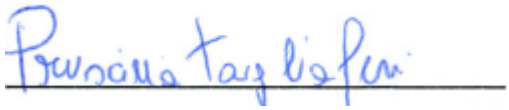
Notified Body identification	
Notified body	**TÜV SÜD Product Service GmbH**
Address:	**Zertifizierstelle – Ridlerstrasse 65, D - 80339 München**
ID Number	**CE0123**
CE Certificate N°	**G21 026056 0031 Rev.01**
Issuing date of EC Certificate	**2025-03-05**
Expiring date of EC Certificate	**2028-02-01**
Conformity assessment procedure	**According to Annex XI, part A**

Place and date of issue of the declaration

Place: Viadana, (MN) Date: 2025-09-03

Name and function of the person who signed

Signature:



Name: Priscilla Tagliaferri

Position: QA&RA Manager, PRRC

This Declaration of Conformity is signed by the above mentioned function, on behalf of:

Name: Gabriele Giovanelli

Signature:

Position: CEO

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Medical devices list of the present EU Declaration of Conformity.

DEVICE CODE	DESCRIPTION (BRAND NAME DEVICE)	BASIC UDI-DI
HM002	FoleyManometer LV	8032248471019F
HM004	SecurMeter	8032248471019F
509936	UnoMeter Abdo-Pressure	8032248471019F
690000-IAP	UROSID IAP Manometer	8032248471019F
HM006	Foley Manometer 6	8032248471019F
HM007	Foley Manometer 7	8032248471019F
HM008	Foley Manometer 8	8032248471019F
HM009	Foley Manometer 9	8032248471019F
HM010	Foley Manometer 10	8032248471019F