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

MEDICAL DEVICE FAMILY:
PERIPHERAL IV CATHETERS and ACCESSORIES

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	Via Guido Rossa N° 20, Viadana (MN), CAP 46019, Italy

The present 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 to 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.

The present EU Declaration of conformity covers all the medical devices listed in Table 1 enclosed to this document which are:

- Device medical device family group: **Peripheral IV Catheters and accessories**
- Intended purpose.
  - **Safety IV Catheters Intended purpose:** Peripheral Venous catheter provided with passive safety mechanism. Peripheral IV Catheter for short term peripheral venous access that, in combination with other medical device, allows the administration of fluids. Once placed in the vein, the IV Catheter can be connected to others medical devices to administer therapeutical solutions or drugs. IV Catheters can be connected with others medical devices provided with luer lock or luer fitting connections such as infusion sets, extension lines, stopcocks and syringes. In case of high pressure administration of fluids, like contrast media, the device is connected to extension lines connected to power injectors to administer the contrast media at high pressure. The Catheter can be used on any patient population while taking into account the vascular anatomy of the patient and of the adequacy of the procedure. The catheters are suitable for use with pressure injectors (max. 325psi). **DO NOT USE 26G IV CATHETERS FOR HIGH PRESSURE TREATMENTS.**

The risk class of the device was determined according to the rules set out in Annex VIII. In particular Peripheral IV Catheters are all Class IIa medical devices.

The devices Peripheral IV Catheters covered by the present declaration are in conformity with EU Regulation 2017/745 requirements.

Peripheral IV Catheters are 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
- EN ISO 10993-12:2021. Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- EN ISO 10993-3:2014. Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-4:2017. Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- EN ISO 10993-5:2009. Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-6:2016. Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
- EN ISO 10993-10:2013. Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- EN ISO 10993-11:2018. Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- EN ISO 10555-1: 2013/A1.2017. Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1
- EN ISO 10555-5: 2013. Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
- EN ISO 23908: 2011. Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- EN ISO 9626: 2016. Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- EN ISO 80369-7:2017. Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- EN ISO 11135:2014 - 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 11607-1:2020- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

- 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 (ISO 11737-2:2009)
- 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)
- 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 IEC 62366-1:2015 – Medical device. Part 1 – Application of usability engineering to medical device
- EN ISO 20417:2021. Medical device. Information to be supplied by the manufacturer

Notified body identification.	
Notified body	**TÜV SÜD Product Service GmbH**
Address:	**Zertifizierstelle – Ridlerstrasse 65, D - 80339 München**
ID Number	**CE0123**
CE Certificate N°	**G20 026056 0032 Rev.00**
Issuing date of EC Certificate	**2023-02-02**
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:2023-02-02

Name and function of the person who signed

Signature:_____

Name: Olga Raschi

Position: QA&RA Manager, PRRC

This declaration of conformity is signed by the above mentioned function, on behalf of:

Name: Gabriele Giovanelli

Position: CEO, Delta Med SpA

Medical devices list of the present EU Declaration of conformity.

DEVICE CODE	DESCRIPTION (BRAND NAME DEVICE)	BASIC UDI-DI
SR+DS2619SD	Surshield Versatus S 26G 19mm	8032248000026D
SR+DS2419SD	Surshield Versatus S 24G 19mm	8032248000026D
SR+DS2225SD	Surshield Versatus S 22G 25mm	8032248000026D
SR+DS2032SD	Surshield Versatus S 20G 32mm	8032248000026D
SR+DS1832SD	Surshield Versatus S 18G 32mm	8032248000026D
SR+DS1845SD	Surshield Versatus S 18G 45mm	8032248000026D
SR+DS1745SD	Surshield Versatus S 17G 45mm	8032248000026D
SR+DS1645SD	Surshield Versatus S 16G 45mm	8032248000026D
SR+DS1445SD	Surshield Versatus S 14G 45mm	8032248000026D
SR+DS2619WD	Surshield Versatus W 26G 19mm	8032248000026D
SR+DS2419WD	Surshield Versatus W 24G 19mm	8032248000026D
SR+DS2225WD	Surshield Versatus W 22G 25mm	8032248000026D
SR+DS2032WD	Surshield Versatus W 20G 32mm	8032248000026D
SR+DS1832WD	Surshield Versatus W 18G 32mm	8032248000026D
SR+DS1845WD	Surshield Versatus W 18G 45mm	8032248000026D
SR+DS1745WD	Surshield Versatus W 17G 45mm	8032248000026D
SR+DS1645WD	Surshield Versatus W 16G 45mm	8032248000026D
SR+DS1445WD	Surshield Versatus W 14G 45mm	8032248000026D
SR+DS2619PD	Surshield Versatus WP 26G 19mm	8032248000026D
SR+DS2419PD	Surshield Versatus WP 24G 19mm	8032248000026D
SR+DS2225PD	Surshield Versatus WP 22G 25mm	8032248000026D
SR+DS2032PD	Surshield Versatus WP 20G 32mm	8032248000026D
SR+DS1832PD	Surshield Versatus WP 18G 32mm	8032248000026D
SR+DS1845PD	Surshield Versatus WP 18G 45mm	8032248000026D
SR+DS1745PD	Surshield Versatus WP 17G 45mm	8032248000026D
SR+DS1645PD	Surshield Versatus WP 16G 45mm	8032248000026D
SR+DS1445PD	Surshield Versatus WP 14G 45mm	8032248000026D