

CERTIFICAZIONI/CERTIFICATES:

ENISO 9001
ENISO 13485
EN ISO 14001
MDSAP 13485:2016
FDA Establishment Registration Number: 3006846316

DECLARATION OF CONFORMITY

MANUFACTURER	DELTA MED SpA Via G. Rossa, 20 – 46019 Viadana (MN)-ITALY Tel.: 0375 785915 - Fax: 0375 785201 – e-mail: info@deltamed.it
DEVICE	Surgical invasive device, not active, for short term use (more than 60 minutes less than 30 days), with the function to guarantee the peripheral venous or subcutaneous access and the blood sampling. Safety device with closed system. Only when the IV Catheter is connected with other medical devices, such as Infusion sets and /or needle less syringes containing solution, it permits the administration at high pressure, excluded the 26G IV Catheters. DISPOSABLE.
DESCRIPTION	Peripheral venous catheters for continuous administration of solutions, fluids, drug even at high pressure or for subcutaneous administration.
FAMILY	I.V. safety catheter with closed system
CLASSIFICATION	REF. MDD 93/42/CEE – ANNEX IX: Class II b – Rule 7 REF. CMDR 98-282 – SCHEDULE I – Class II REF. CND: C0101999 – Cateteri Venosi periferici – Altri (Dispositivi per Sistema artero-venoso – Cateteri venosi periferici)

We DELTA MED SpA hereby declare, under our full and sole responsibility that the medical devices, code number, items below listed are conform to the Essential Requirements of Annex I of the **Medical Device Directive** and to the harmonized applicable norms:

DIRECTIVE 93/42/EEC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF THE 14 JUNE 1993 CONCERNING MEDICALS DEVICES ACKNOWLEDGED BY THE ITALIAN REPUBLIC WITH LEGISLATIVE DECREE IN FORCE FROM **24 FEBRUARY 1997, N. 46** AND FOLLOWING CHANGES AND INTEGRATION OF **DIRECTIVE 2007/47/EEC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ACKNOWLEDGED BY THE ITALIAN REPUBLIC WITH THE LEGISLATIVE DECREE N° 37 OF 25 JANUARY 2010** AND TO ANNEX II (EXCLUDING 4) AND ANNEX VII.

All the technical documentation is available by the Manufacturer site and could be examined by the Competent Authority and Notified Body.

DELTA MED SpA defined a post market vigilance and monitoring procedure of those medical devices hereby listed according to **European Guidelines MEDDEV 2.12.rev. 8 – January 2013** and according to **Regulation (EU) 2017/745 for the requirements defined in Articles from 87 up to Article 90**. Requirements defined in Article 92 will be implemented when EUDAMED will be fully functional.

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DESCRIPTION	Peripheral venous catheters for continuous administration of solutions, fluids, drug even at high pressure or for subcutaneous administration.
FAMILY	Safety I.V. Catheter with closed system
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Among main Norms applied by Delta Med SpA, are the following:

Quality System Management: **EN ISO 13485:2016 e EN ISO 9001:2015.**

Standard applied to the product: **EN ISO 15223-1:2021 — UNI CEI EN ISO 1041:2013 — EN ISO 80369-7:2021— EN ISO 14971:2019 — UNI EN ISO 10555-1:2013 + Correz. 2014 – UNI EN ISO 10555-5:2013 EN ISO 11607 — EN ISO 11737 - EN ISO 10993 — UNI EN ISO 11135-1:2014+A1.2019 – EN ISO 8536-4:2020 – UNI EN ISO 8536-9:2015**

Furthermore, among reference Standard applied we follow: **EN ISO 14644, EN ISO 14698.**

The complete list of the norms and product standard applied is reported in the check list of essential requirements in the Technical File.

Notified Body: **TÜV SÜD Product Service GmbH**

Address: **Zertifizierstelle – Ridlerstrasse 65, D - 80339 München**

ID Number: **0123**

Certificate no: **G1 026056 022 rev.2 Issued: 2021-04-20 Expiring: 2024-05-26**

Place and date: Viadana (MN), 02nd September 2022

This declaration is valid until: 26 May 2024

Stamp and signature

Name: **Olga Raschi**

Position: **Quality Assurance Manager**

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LIST OF MEDICAL DEVICES COVERED BY THIS DECLARATION

CODE	MODEL	DESCRIPTION
3904722	DELTA VEN 26G 19MM	IV safety catheter in polyurethane with closed system 26G 19mm sterile
3914722	DELTA VEN 24G 19MM	IV safety catheter in polyurethane with closed system 24G 19mm sterile
3915722	DELTA VEN 24G 25MM	IV safety catheter in polyurethane with closed system 24G 25mm sterile
3924722	DELTA VEN 22G 19MM	IV safety catheter in polyurethane with closed system 22G 19mm sterile
3925722	DELTA VEN 22G 25MM	IV safety catheter in polyurethane with closed system 22G 25mm sterile
3926722	DELTA VEN 22G 32MM	IV safety catheter in polyurethane with closed system 22G 32mm sterile
3927722	DELTA VEN 22G 45MM	IV safety catheter in polyurethane with closed system 22G 45mm sterile
3935722	DELTA VEN 20G 25MM	IV safety catheter in polyurethane with closed system 20G 25mm sterile
3936722	DELTA VEN 20G 32MM	IV safety catheter in polyurethane with closed system 20G 32mm sterile
3937722	DELTA VEN 20G 45MM	IV safety catheter in polyurethane with closed system 20G 45mm sterile
3938722	DELTA VEN 20G 57MM	IV safety catheter in polyurethane with closed system 20G 57mm sterile
3945722	DELTA VEN 18G 25MM	IV safety catheter in polyurethane with closed system 18G 25mm sterile
3946722	DELTA VEN 18G 32MM	IV safety catheter in polyurethane with closed system 18G 32mm sterile

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LIST OF MEDICAL DEVICES COVERED BY THIS DECLARATION

CODE	MODEL	DESCRIPTION
3947722	DELTA VEN 18G 45MM	IV safety catheter in polyurethane with closed system 18G 45mm sterile
3948722	DELTA VEN 18G 57MM	IV safety catheter in polyurethane with closed system 18G 57mm sterile
3956722	DELTA VEN 16G 32MM	IV safety catheter in polyurethane with closed system 16G 32mm sterile