

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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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), 2nd 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
3900522	DELTAVEN Y 26G 19MM	IV safety catheter in polyurethane with closed system 26G 19mm with final Y connection, air drainage system and male L/L cap, sterile.
3911022	DELTAVEN Y 24G 19MM	IV safety catheter in polyurethane with closed system 24G 19mm with final Y connection, air drainage system and male L/L cap, sterile.
3911222	DELTAVEN Y 24G 25MM	IV safety catheter in polyurethane with closed system 24G 25mm with final Y connection, air drainage system and male L/L cap, sterile.
3920522	DELTAVEN Y 22G 19MM	IV safety catheter in polyurethane with closed system 22G 19mm with final Y connection, air drainage system and male L/L cap, sterile.
3921522	DELTAVEN Y 22G 25MM	IV safety catheter in polyurethane with closed system 22G 25mm with final Y connection, air drainage system and male L/L cap, sterile.
3922522	DELTAVEN Y 22G 32MM	IV safety catheter in polyurethane with closed system 22G 32mm with final Y connection, air drainage system and male L/L cap, sterile.
3923522	DELTAVEN Y 22G 45MM	IV safety catheter in polyurethane with closed system 22G 45mm with final Y connection, air drainage system and male L/L cap, sterile.
3931522	DELTAVEN Y 20G 25MM	IV safety catheter in polyurethane with closed system 20G 25mm with final Y connection, air drainage system and male L/L cap, sterile.
3932522	DELTAVEN Y 20G 32MM	IV safety catheter in polyurethane with closed system 20G 32mm with final Y connection, air drainage system and male L/L cap, sterile.

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LIST OF MEDICAL DEVICES COVERED BY THIS DECLARATION

CODE	MODEL	DESCRIPTION
3933522	DELTAVEN Y 20G 45MM	IV safety catheter in polyurethane with closed system 20G 45mm with final Y connection, air drainage system and male L/L cap, sterile.
3934522	DELTAVEN Y 20G 57MM	IV safety catheter in polyurethane with closed system 20G 57mm with final Y connection, air drainage system and male L/L cap, sterile.
3941522	DELTAVEN Y 18G 25MM	IV safety catheter in polyurethane with closed system 18G 25mm with final Y connection, air drainage system and male L/L cap, sterile.
3942522	DELTAVEN Y 18G 32MM	IV safety catheter in polyurethane with closed system 18G 32mm with final Y connection, air drainage system and male L/L cap, sterile.
3943522	DELTAVEN Y 18G 45MM	IV safety catheter in polyurethane with closed system 18G 45mm with final Y connection, air drainage system and male L/L cap, sterile.
3944522	DELTAVEN Y 18G 57MM	IV safety catheter in polyurethane with closed system 18G 57mm with final Y connection, air drainage system and male L/L cap, sterile.
3952522	DELTAVEN Y 16G 32MM	IV safety catheter in polyurethane with closed system 16G 32mm with final Y connection, air drainage system and male L/L cap, sterile.