

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) Tel.: 0375 785915 - Fax: 0375 785201 – e-mail: info@deltamed.biz
FACILITY	Business Unit DELTA MED SpA – B.U. I.V.C. Via G.Rossa, 20 – 46019 Viadana (MN) Tel.: 0375 785915 – Fax: 0375 785201 – e-mail: info@deltamed.biz
DEVICE	Surgical invasive medical device not active for short term usage (more than 60 minutes, lower than 30 days), with function of peripheral endovenous admistration. Device for peripheral endovenous catheterization. Only if connection with other medical devices such as infusion set and/or needleless syringes containing a solution it permits the administration. — DISPOSABLE.
DESCRIPTION	Device for peripheral endovenous catheterization.
FAMILY	I.V. Catheter single entry or dual entry.
CLASSIFICATION	(RIF. MDD 93/42/CEE – ANNEX IX: Classe II a – Rule 7 RIF. CMDR 98-282 – SCHEDULE I – Class II RIF. CND: C0101010201 – Aghi cannula di sicurezza con valvola d’iniezione RIF. CND: C0101010202 – Aghi cannula di sicurezza senza valvola d’iniezione (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 norms applicable:

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 FEBBRAIO 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.

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

DELTA MED SpA has 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.**

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Among main Norms-with regards to MDD 93/42/EC applied by Delta Med SpA, are the following:

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

Standards for the product: UNI CEI EN ISO 15223-1:2017 –UNI CEI EN 1041:2013
 UNI CEI EN ISO 80369-7:2017 – UNI CEI EN ISO 14971:2012 – UNI EN ISO 9626:2016
 – Serie norme UNI EN ISO 11607 – Serie norme UNI EN ISO 11737 – Serie norme UNI
 EN ISO 11138 – Serie norme UNI EN ISO 10993 – UNI EN ISO 10555-1:2018 – UNI EN
 ISO 10555-5:2013 – UNI EN ISO 11135:2014 – UNI EN ISO 23908:2013

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: **Istituto Superiore di Sanità**

Address: Via Regina Elena, 299 — 00161 ROMA

ID number: **0373**

CE Certificate: **QPZ-1899-17 issued on 14/12/2017 expiry: 13/12/2022**

Addendum QPZ-1899-17 Add. 08-20 – issued on: 14/09/2020 expiry: 13/12/2022

Place and date: Viadana (MN), 15/09/2020



Stamp and Signature
Name: Raschi Olga
Position: Quality Assurance Manager



DELTA MED S.P.A.
 MEDICAL DEVICES
 Via G. Rossa, 20 - I 46019 Viadana (Mn)
 Tel. 0375.785915 - Fax 0375.785201
 P.IVA e C. Fisc. 01693020206

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LIST OF MEDICAL DEVICES OBJECT OF THIS DECLARATION

CODE	MODEL	DESCRIPTION
SR+DS2619SD	Surshield Versatus S 26G 19mm	Single entry I.V.catheter without wings 26G 19mm PUR safety
SR+DS2419SD	Surshield Versatus S 24G 19mm	Single entry I.V.catheter without wings 24G 19mm PUR safety
SR+DS2225SD	Surshield Versatus S 22G 25mm	Single entry I.V.catheter without wings 22G 25mm PUR safety
SR+DS2032SD	Surshield Versatus S 20G 32mm	Single entry I.V.catheter without wings 20G 32mm PUR safety
SR+DS1832SD	Surshield Versatus S 18G 32mm	Single entry I.V.catheter without wings 18G 32mm PUR safety
SR+DS1845SD	Surshield Versatus S 18G 45mm	Single entry I.V.catheter without wings 18G 45mm PUR safety
SR+DS1745SD	Surshield Versatus S 17G 45mm	Single entry I.V.catheter without wings 17G 45mm PUR safety
SR+DS1645SD	Surshield Versatus S 16G 45mm	Single entry I.V.catheter without wings 16G 45mm PUR safety
SR+DS1445SD	Surshield Versatus S 14G 45mm	Single entry I.V.catheter without wings 14G 45mm PUR safety
SR+DS2619WD	Surshield Versatus W 26G 19mm	Single entry I.V.catheter with wings 26G 19mm PUR safety
SR+DS2419WD	Surshield Versatus W 24G 19mm	Single entry I.V.catheter with wings 24G 19mm PUR safety
SR+DS2225WD	Surshield Versatus W 22G 25mm	Single entry I.V.catheter with wings 22G 25mm PUR safety
SR+DS2032WD	Surshield Versatus W 20G 32mm	Single entry I.V.catheter with wings 20G 32mm PUR safety
SR+DS1832WD	Surshield Versatus W 18G 32mm	Single entry I.V.catheter with wings 18G 32mm PUR safety
SR+DS1845WD	Surshield Versatus W 18G 45mm	Single entry I.V.catheter with wings 18G 45mm PUR safety
SR+DS1745WD	Surshield Versatus W 17G 45mm	Single entry I.V.catheter with wings 17G 45mm PUR safety
SR+DS1645WD	Surshield Versatus W 16G 45mm	Single entry I.V.catheter with wings 16G 45mm PUR safety
SR+DS1445WD	Surshield Versatus W 14G 45mm	Single entry I.V.catheter with wings 14G 45mm PUR safety

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LIST OF MEDICAL DEVICES OBJECT OF THIS DECLARATION

MODEL	MODEL	MODEL
SR+DS2619PD	Surshield Versatus WP 26G 19mm	Dual entry I.V.catheter 26G 19mm PUR safety
SR+DS2419PD	Surshield Versatus WP 24G 19mm	Dual entry I.V.catheter 24G 19mm PUR safety
SR+DS2225PD	Surshield Versatus WP 22G 25mm	Dual entry I.V.catheter 22G 25mm PUR safety
SR+DS2032PD	Surshield Versatus WP 20G 32mm	Dual entry I.V.catheter 20G 32mm PUR safety
SR+DS1832PD	Surshield Versatus WP 18G 32mm	Dual entry I.V.catheter 18G 32mm PUR safety
SR+DS1845PD	Surshield Versatus WP 18G 45mm	Dual entry I.V.catheter 18G 45mm PUR safety
SR+DS1745PD	Surshield Versatus WP 17G 45mm	Dual entry I.V.catheter 17G 45mm PUR safety
SR+DS1645PD	Surshield Versatus WP 16G 45mm	Dual entry I.V.catheter 16G 45mm PUR safety
SR+DS1445PD	Surshield Versatus WP 14G 45mm	Dual entry I.V.catheter 14G 45mm PUR safety