

1. Renseignements administratifs concernant l'entreprise		Date de mise à jour : NA Date d'édition : 26/05/2025
1.1	Nom : TERUMO FRANCE SAS	
1.2	Adresse complète : Bâtiment Atria 1 Avenue Edouard Belin 92500 Reuil Malmaison	<i>Tel</i> : 0 800 90 50 42 <i>Fax</i> : 01 30 96 12 90 <i>E-mail</i> : service-client@terumo-europe.com <i>Site internet</i> : www.terumo-europe.com
1.3	Coordonnées du correspondant matériovigilance : Mme Sabrina Feddag Rarrbo	<i>Tel</i> : 0 800 90 50 42 <i>Fax</i> : 01 30 96 12 90 <i>E-mail</i> : materiovigilancefr@terumo-europe.com
2. Informations sur le dispositif ou équipement		
2.1	Dénomination commune : Obturbateurs pour cathéters Intraveineux	
2.2	Dénomination commerciale : Obturbateur Terumo pour Cathéters I.V.	
2.3	Code CLADIMED : C54LA - OBTURATEUR BOUCHON	
2.4	Code LPPR* (ex TIPS si applicable) : Non applicable * « liste des produits et prestations remboursables » inscrits sur la liste prévue à l'article L 165-1	
2.5	Classe du DM : IIa Directive ou règlement de l'UE applicable : MDR 2017/745 Selon Annexe n° XI, Partie A Numéro de l'organisme notifié : 0123 Fabricant du DM : DELTA MED SPA Via Guido Rossa n°20, Viadana (MN), CAP 46019, ITALY La déclaration de conformité CE est disponible dans l'annexe I du présent document. Le certificat de marquage CE est disponible dans l'annexe II du présent document. Le certificat EN ISO 13485 :2016 est disponible dans l'annexe III du présent document.	
2.6	Descriptif du dispositif : L'obturbateur pour cathéter intraveineux permet de fermer le cathéter et d'éviter la formation de caillots pendant une perfusion intermittente. Un obturbateur de même code couleur que le cathéter est disponible pour chaque taille.	
2.7	Références Catalogue : Voir le tableau des spécifications produits disponible dans l'annexe V du présent document.	

2.8	Composition du dispositif et Accessoires : <table> <tr> <th>Description</th><th>Matériaux</th></tr> <tr> <td>Obturateur</td><td>Polypropylène</td></tr> <tr> <td>Protection</td><td>Polyéthylène</td></tr> </table> Ne contient aucun composant fabriqué à partir de PVC ou de latex naturel.	Description	Matériaux	Obturateur	Polypropylène	Protection	Polyéthylène
Description	Matériaux						
Obturateur	Polypropylène						
Protection	Polyéthylène						
2.9	Domaine - Indications : Cet accessoire permet l'occlusion complète du tube et du corps du cathéter afin d'assurer la fermeture et la suspension de l'administration. Domaine d'utilisation : Occlusion complète du tube et corps de cathéter intraveineux.						
3. Procédé de stérilisation :							
3.1	DM stérile : OUI Mode de stérilisation du dispositif : Stérilisé à l'Oxyde d'Éthylène						
4. Conditions de conservation et de stockage							
4.1	Conditions normales de conservation & de stockage : - Ne pas utiliser si l'emballage est endommagé ou ouvert ou si la date d'expiration est dépassée. - Ne pas stocker à des températures extrêmes et à l'humidité Précautions particulières : - Ne pas utiliser si l'emballage est endommagé - Ne pas réutiliser/ne pas restériliser - Éliminer en toute sécurité après usage unique pour éviter tout risque d'infection Veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document. Durée de la validité du produit : 5 ans. Le numéro de lot et la date de péremption sont imprimés sur le papier de l'emballage thermoformé, veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document.						
5. Sécurité d'utilisation							
5.1	Sécurité technique : Veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document.						
5.2	Sécurité biologique (s'il y a lieu) : Veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document.						
6. Conseils d'utilisation							
6.1	Mode d'emploi : Veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document.						
6.2	Indications : Accessoire destiné à être utilisé en combinaison uniquement et exclusivement avec les cathéters intraveineux Terumo à simple et double entrée. Cet accessoire permet l'occlusion complète du tube et du corps du cathéter afin d'assurer la fermeture et la suspension de l'administration.						
6.3	Précautions d'emploi : Veuillez-vous référer à l'étiquetage en vigueur, disponible en annexe IV de ce présent document.						

6.4	Contre- Indications : Ne pas utiliser chez les patients présentant une hypersensibilité connue aux matériaux utilisés.
7. Informations complémentaires sur le produit	
	Non applicable.
8. Liste des annexes au dossier (s'il y a lieu)	
	Annexe I : Déclaration de Conformité CE Annexe II : Certificat(s) de marquage CE Annexe III : Certificat EN ISO 13485 :2016 Annexe IV : Etiquetage Annexe V : Spécifications des produits
9. Images (s'il y a lieu)	
	Non Applicable.

Annexe I

Déclaration de Conformité CE

CERTIFICAZIONI/CERTIFICATES:

EN ISO 9001

EN ISO 13485

EN ISO 14001

MDSAP 13485:2016

FDA Establishment Registration Number: 3006846316

**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.

Intended purpose of the accessories

Obturator: Accessory intended to be used in combination only and exclusively with Delta Med single and dual entry IV catheters. This accessory allows complete occlusion of the catheter tube and catheter body in order to ensure closure and suspension of administration.

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

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

Peripheral IV Catheters and accessories are in compliance with the following standards used and in relation to which conformity is declared:

CERTIFICAZIONI/CERTIFICATES:

EN ISO 9001

EN ISO 13485

EN ISO 14001

MDSAP 13485:2016

FDA Establishment Registration Number: 3006846316

- o EN ISO 13485:2016/A11.2021 - Harmonized standard - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016).
- o EN ISO 14971:2019/A11.2021 - Medical devices - Application of risk management to medical devices
- o EN ISO 10993-12:2021. Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- o EN ISO 10993-3:2014. Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- o EN ISO 10993-4:2017. Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- o EN ISO 10993-5:2009. Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- o EN ISO 10993-6:2016. Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
- o EN ISO 10993-10:2013. Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- o EN ISO 10993-11:2018. Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- o EN ISO 10555-1: 2013/A1.2017. Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1
- o EN ISO 10555-5: 2013. Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
- o ISO 14972: 1998. Sterile obturators for single use with over-needle peripheral intravascular catheters
- o 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.
- o EN ISO 9626: 2016. Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- o EN ISO 80369-7:2017. Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- o 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
- o EN ISO 11607-1:2020- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- o EN ISO 11607-2:2020 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- o EN ISO 11737-1:2018 - Sterilization of health care products - Microbiological methods Determination of a population of microorganisms on products
- o 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)
- o EN ISO 11138-1:2017 - Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
- o 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)
- o 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.
- o EN IEC 62366-1:2015 – Medical device. Part 1 – Application of usability engineering to medical device
- o EN ISO 20417:2021. Medical device. Information to be supplied by the manufacturer

CERTIFICAZIONI/CERTIFICATES:

EN ISO 9001

EN ISO 13485

EN ISO 14001

MDSAP 13485:2016

FDA Establishment Registration Number: 3006846316

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: 2023-06-26

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 Giovannelli

Position: CEO, Delta Med SpA

CERTIFICAZIONI/CERTIFICATES:

EN ISO 9001

EN ISO 13485

EN ISO 14001

MDSAP 13485:2016

FDA Establishment Registration Number: 3006846316

Medical devices list of the present EU Declaration of conformity.

DEVICE CODE	DESCRIPTION (BRAND NAME DEVICE)	BASIC UDI-DI
SO+DM2419PD	Obt. Terumo Dual entry 24G 19mm	8032248400007P
SO+DM2225PD	Obt. Terumo Dual entry 22G 25mm	8032248400007P
SO+DM2032PD	Obt. Terumo Dual entry 20G 32mm	8032248400007P
SO+DM1845PD	Obt. Terumo Dual entry 18G 45mm	8032248400007P
SO+DM1745PD	Obt. Terumo Dual entry 17G 45mm	8032248400007P
SO+DM1645PD	Obt. Terumo Dual entry 16G 45mm	8032248400007P
SO+DM1445PD	Obt. Terumo Dual entry 14G 45mm	8032248400007P
SO+DM1832PD	Obt. Terumo Dual entry 18G 32mm	8032248400007P
SO+DM2419WD	Obt. Terumo Single entry 24G 19mm	8032248400007P
SO+DM2225WD	Obt. Terumo Single entry 22G 25mm	8032248400007P
SO+DM2032WD	Obt. Terumo Single entry 20G 32mm	8032248400007P
SO+DM1845WD	Obt. Terumo Single entry 18G 45mm	8032248400007P
SO+DM1745WD	Obt. Terumo Single entry 17G 45mm	8032248400007P
SO+DM1645WD	Obt. Terumo Single entry 16G 45mm	8032248400007P
SO+DM1445WD	Obt. Terumo Single entry 14G 45mm	8032248400007P
SO+DM1832WD	Obt. Terumo Single entry 18G 32mm	8032248400007P

Annexe II

Marquage CE



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 026056 0032 Rev. 00

Manufacturer:**Delta Med S.p.a.**

Via Guido Rossa 20
46019 Viadana (MN)
ITALY

SRN Manufacturer:

IT-MF-000027962

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G20 026056 0032 Rev. 00

Report No.:

ITA1902043

Valid from:

2023-02-02

Valid until:

2028-02-01

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-02-02



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 026056 0032 Rev. 00

Classification:

IIa

Device Group:

A010599 - OPHTHALMOLOGY INJECTION NEEDLES AND KITS
- OTHER
A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
A070502 - CAPS OR OBTURATORS, PERFORABLE
C010101 - PERIPHERAL I.V. CATHETERS

The validity of this certificate \
depends on conditions and/or
is limited to the following:

Annexe III

Certificat EN ISO 13485 : 2016



Product Service

Certificate

No. Q5 026056 0024 Rev. 03

Holder of Certificate: **Delta Med S.p.a.**
Via Guido Rossa 20
46019 Viadana (MN)
ITALY

Certification Mark:



Scope of Certificate:

Design and development, production, sales and distribution of sterile medical devices: infusion sets, intravenous and arterial catheters, epicranial needles, ophthalmic needles and related accessories.

Production, sales and distribution of custom packs for diagnosis and surgery, sterile and non-sterile non-woven medical devices for surgical theatre.

Distribution and sales of sterile medical devices and kits: intravenous and arterial catheters, bandages, elastomeric pumps.

Contract manufacturing of plastic medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 026056 0024 Rev. 03

Report No.: ITA1476022272

Valid from: 2024-04-01
Valid until: 2027-03-31

Date, 2024-02-27

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 026056 0024 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Delta Med S.p.a.**
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

Design and development, production, sales and distribution of sterile medical devices: infusion sets, intravenous and arterial catheters, epicranial needles, ophthalmic needles and related accessories.
Production, sales and distribution of custom packs for diagnosis and surgery, sterile and non-sterile non-woven medical devices for surgical theatre.
Distribution and sales of sterile medical devices and kits: intravenous and arterial catheters, bandages, elastomeric pumps.
Contract manufacturing of plastic medical devices.

Delta Med S.p.A.
Via Emilio Segrè 6, 42041 Sorbolo a Levante di Brescello RE, ITALY

Production of sterile medical devices: intravenous and arterial catheters and related accessories.

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Annexe IV

Etiquetage

Copy of the layout for the labels of Obturator for I.V. catheter with injection port

Unit box label:

OBTURATOR FOR I.V. CATHETER WITH INJECTION PORT SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP 14G 2.00 x 45 mm REF SO+DM1445PD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40031 4 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITH INJECTION PORT SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP 16G 1.75 x 45 mm REF SO+DM1645PD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40030 7 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO
OBTURATOR FOR I.V. CATHETER WITH INJECTION PORT SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP 17G 1.50 x 45 mm REF SO+DM1745PD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40029 1 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITH INJECTION PORT SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP 18G 1.30 x 32 mm REF SO+DM1832PD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40032 1 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

18G 1.30 x 45 mm

REF SO+DM1845PD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40028 4
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

20G 1.00 x 32 mm

REF SO+DM2032PD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40027 7
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

22G 0.90 x 25 mm

REF SO+DM2225PD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40026 0
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

24G 0.74 x 19 mm

REF SO+DM2419PD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40025 3
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

Shipping Carton label:

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

14G 2.00 x 45 mm

REF SO+DM1445PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40031 8
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

CE 0123 **MD**

STERILE EO

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

16G 1.75 x 45 mm

REF SO+DM1645PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40030 1
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

CE 0123 **MD**

STERILE EO

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

17G 1.50 x 45 mm

REF SO+DM1745PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40029 5
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

CE 0123 **MD**

STERILE EO

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

18G 1.30 x 32 mm

REF SO+DM1832PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40032 5
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

CE 0123 **MD**

STERILE EO

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

18G 1.30 x 45 mm

REF SO+DM1845PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40028 8
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

20G 1.00 x 32 mm

REF SO+DM2032PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40027 1
(10) 1130000
(17) 280229
(11) 230301

DELTA MED S.p.A.
Via Guido Rossa 20, 46019 Viadana (MN), ITALY

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

CE 0123

MD

STERILE EO

CH REP CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

22G 0.90 x 25 mm

REF SO+DM2225PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40026 4
(10) 1130000
(17) 280229
(11) 230301

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STERILE EO

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Bahnhofstrasse 32
CH-6300 Zug, Switzerland

OBTURATOR
FOR I.V. CATHETER WITH INJECTION PORT
SURFLO-WP / VERSATUS-WP / Surshield VERSATUS-WP

24G 0.74 x 19 mm

REF SO+DM2419PD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40025 7
(10) 1130000
(17) 280229
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Copy of the layout for the labels of Obturator for I.V. catheter without injection port

Unit box label:

OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 14G 2.00 x 45 mm REF SO+DM1445WD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40055 0 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 16G 1.75 x 45 mm REF SO+DM1645WD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40054 3 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO
OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 17G 1.50 x 45 mm REF SO+DM1745WD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40053 6 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 18G 1.30 x 32 mm REF SO+DM1832WD LOT 1130000 2028-02-29 2023-03-01 (01) 3 80 32248 40056 7 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO

OBTURATOR
FOR I.V. CATHETER WITHOUT INJECTION PORT
SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W /
VERSATUS-W / Surshield VERSATUS-S/-W

18G 1.30 x 45 mm

REF SO+DM1845WD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40052 9
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CH-8300 Zug, Switzerland

CE 0123 **MD** **STERILE EO**

OBTURATOR
FOR I.V. CATHETER WITHOUT INJECTION PORT
SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W /
VERSATUS-W / Surshield VERSATUS-S/-W

20G 1.00 x 32 mm

REF SO+DM2032WD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40051 2
(10) 1130000
(17) 280229
(11) 230301

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CH-8300 Zug, Switzerland

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OBTURATOR
FOR I.V. CATHETER WITHOUT INJECTION PORT
SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W /
VERSATUS-W / Surshield VERSATUS-S/-W

22G 0.90 x 25 mm

REF SO+DM2225WD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40050 5
(10) 1130000
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VERSATUS-W / Surshield VERSATUS-S/-W

24G 0.74 x 19 mm

REF SO+DM2419WD

LOT 1130000

2028-02-29 2023-03-01

(01) 3 80 32248 40049 9
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Shipping Carton label:

OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 14G 2.00 x 45 mm REF SO+DM1445WD LOT 1130000 2028-02-29 2023-03-01 (01) 5 80 32248 40055 4 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 16G 1.75 x 45 mm REF SO+DM1645WD LOT 1130000 2028-02-29 2023-03-01 (01) 5 80 32248 40054 7 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO
OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 17G 1.50 x 45 mm REF SO+DM1745WD LOT 1130000 2028-02-29 2023-03-01 (01) 5 80 32248 40053 0 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO	OBTURATOR FOR I.V. CATHETER WITHOUT INJECTION PORT SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W / VERSATUS-W / Surshield VERSATUS-S/-W 18G 1.30 x 32 mm REF SO+DM1832WD LOT 1130000 2028-02-29 2023-03-01 (01) 5 80 32248 40056 1 (10) 1130000 (17) 280229 (11) 230301 DELTA MED S.p.A. Via Guido Rossa 20, 46019 Viadana (MN), ITALY TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM CH REP CMC Medical Devices GmbH Bahnhofstrasse 32 CH-6300 Zug, Switzerland CE 0123 MD STERILE EO

OBTURATOR
FOR I.V. CATHETER WITHOUT INJECTION PORT
SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W /
VERSATUS-W / Surshield VERSATUS-S/-W

18G 1.30 x 45 mm

REF SO+DM1845WD

LOT 1130000

2028-02-29 2023-03-01

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CE 0123 **MD** **STERILE EO**

OBTURATOR
FOR I.V. CATHETER WITHOUT INJECTION PORT
SURFLO-S Plus / VERSATUS-S Plus / SURFLO-W /
VERSATUS-W / Surshield VERSATUS-S/-W

20G 1.00 x 32 mm

REF SO+DM2032WD

LOT 1130000

2028-02-29 2023-03-01

(01) 5 80 32248 40051 6
(10) 1130000
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VERSATUS-W / Surshield VERSATUS-S/-W

22G 0.90 x 25 mm

REF SO+DM2225WD

LOT 1130000

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24G 0.74 x 19 mm

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Annexe V

Spécifications des produits

	Nom Commercial	Obturbateur pour cathéter IV								
	Références	Dimensions			Code couleur	Code IUD-ID	Emballage unitaire	UCD	Conditionnement	QML
		Taille de l'obturbateur		Longueur						
	SO+DM1445PD	14G	2.00mm	45mm	Orange	58032248400318	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1445WD	14G	2.00mm	45mm	Orange	58032248400554	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1645PD	16G	1.75mm	45mm	Gris	58032248400301	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1645WD	16G	1.75mm	45mm	Gris	58032248400547	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1745PD	17G	1.50mm	45mm	Blanc	58032248400295	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1745WD	17G	1.50mm	45mm	Blanc	58032248400530	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM18332PD	18G	1.30mm	32mm	Vert	58032248400325	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1832WD	18G	1.30mm	32mm	Vert	58032248400561	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1845PD	18G	1.30mm	45mm	Vert	58032248400288	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM1845WD	18G	1.30mm	45mm	Vert	58032248400523	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM2032PD	20G	1.00mm	32mm	Rose	58032248400271	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM2032WD	20G	1.00mm	32mm	Rose	58032248400516	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM2225PD	22G	0.90mm	25mm	Bleu	58032248400264	Emballage thermoformé	50	50 pièces/ boîte	500
	SO+DM2225WD	22G	0.90mm	25mm	Bleu	58032248400509	Emballage thermoformé	50	50 pièces/ boîte	500
SO+DM2419PD	24G	0.74mm	19mm	Jaune	58032248400257	Emballage thermoformé	50	50 pièces/ boîte	500	
SO+DM2419WD	24G	0.74mm	19mm	Jaune	58032248400493	Emballage thermoformé	50	50 pièces/ boîte	500	

UCD (Unité de Commande)

CDT (Multiple de l'UCD)

QML (Quantité minimale de livraison)

Pour les références avec la lettre :

- W : **pour cathéter IV sans site d'injection**
 - o SURFLO™-S Plus
 - o VERSATUS-S Plus
 - o SURFLO™-W
 - o VERSATUS-W
 - o Surshield™ VERSATUS-S/-W

- P : **pour cathéter IV avec site d'injection**
 - o SURFLO™ WP
 - o VERSATUS-WP
 - o Surshield™ VERSATUS-WP

AQ LTF-004A [1]

Mise à jour du 05/11/2020 – EUROPHARMAT - Dossier DM-Grille- 01-2020.doc