ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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. 01

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, Certification, Validation and Verification Regulations 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. 01

Report No.:	ITA1473829389_CN
Preceding Certificate No.:	G20 026056 0032 Rev. 00
Valid from:	2025-03-05
Valid until:	2028-02-01
Date of Initial Issuance:	2023-02-02

Issue date: 2025-03-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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. 01

Classification: Class IIa

Device Group:
A010302 - PLEXUS BLOCK NEEDLES AND KITS
A010599 - OPHTHALMOLOGY INJECTION NEEDLES AND KITS - OTHER
A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
A070502 - CAPS OR OBTURATORS, PERFORABLE
B030202 - CYTAPHERESIS DEVICES AND KITS
C010101 - PERIPHERAL I.V. CATHETERS
C010180 - PERIPHERAL I.V. CATHETERS AND CANNULAS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
C0199 - ARTERIO-VENOUS DEVICES - OTHER
Q0199 - ODONTOLOGY DEVICES - OTHER
U010299 - URETHRAL PROSTATIC AND BLADDER CATHETERS, WITH BALLOON - OTHER
U050101 - CYSTOMANOMETRY CATHETERS, WITHOUT BALLOON
U050199 - CYSTOMANOMETRY AND URETHROMANOMETRY CATHETERS - OTHER
U050202 - BLADDER PRESSURE-FLOW STUDY CATHETERS
U050402 - INTRA-ABDOMINAL PRESSURE MEASUREMENT CATHETERS, WITH BALLOON
U0580 - URODYNAMICS DEVICES - ACCESSORIES
V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER

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

Revision History:

Rev.	Dated	Report	Description
00	2023-02-02	ITA1902043	-
01	2025-03-05	ITA1473829389_CN	Supplemented: Device(s)/group of device(s) added

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Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 026056 0031 Rev. 01

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. 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.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G21 026056 0031 Rev. 01

Report No.:	ITA1473829389_CN
Preceding Certificate No.:	G21 026056 0031 Rev. 00
Valid from:	2025-03-05
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TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 026056 0031 Rev. 01

Classification:	Class I
Device Group:	A030101 - INFUSION CONTROLLERS A030201 - EXTENSIONS A0380 - TUBULAR DEVICES - ACCESSORIES A0703 - STOPCOCKS A070501 - CAPS OR OBTURATORS, NON-PERFORABLE A070502 - CAPS OR OBTURATORS, PERFORABLE T020101 - INCISION DRAPES T020102 - SPECIALISTIC SURGERY DRAPES T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS) T020401 - STANDARD SURGICAL GOWNS T020402 - REINFORCED SURGICAL GOWNS T0210 - NON-SURGICAL DRAPES T0299 - PROTECTION DRAPES AND GARMENTS - OTHER T030101 - COVER CAPS, INSTRUMENTS AND EQUIPMENT T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER U050401 - INTRA-ABDOMINAL PRESSURE MEASUREMENT CATHETERS, WITHOUT BALLOON U0580 - URODYNAMICS DEVICES - ACCESSORIES V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function

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Revision History:

Rev.	Dated	Report	Description
00	2023-02-02	ITA1902043	-
01	2025-03-05	ITA1473829389_CN	Supplemented: Device(s)/group of device(s) added

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