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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 026056 0030 Rev. 02

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

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Sterile Medical Devices: Infusion Sets, Intravenous and Artherial Catheters, Epicranical Needles, Opthalmic Needles, Caps and Otturators; Production and Distribution of Packs for Diagnosis and Surgery (Composed by Needles, Catheters, Blades, Clamps, Drapes, Gowns, Infusion Sets, Aspiration and Irrigation Systems, Bands); Sterile and Non-Sterile Non-Woven Drapes, Gowns, Cuffs and Sheets for Surgical Theatre**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 026056 0030 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001213**
Report No.: **ITA1476022272**
Effective Date: **2024-01-23**
Expiry Date: **2027-01-22**

Date of Issue: 2024-01-30

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

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

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

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C E R T I F I C A T E

No. QS6 026056 0030 Rev. 02

Facility Scopes:

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

Design and Development, Production and Distribution of Sterile Medical Devices: Infusion Sets, Intravenous and Artherial Catheters, Epicranical Needles, Opthalmic Needles, Caps and Otturators; Production and Distribution of Packs for Diagnosis and Surgery (Composed by Needles, Catheters, Blades, Clamps, Drapes, Gowns, Infusion Sets, Aspiration and Irrigation Systems, Bands); Sterile and Non-Sterile Non-Woven Drapes, Gowns, Cuffs and Sheets for Surgical Theatre
REPs Facility ID: F001213

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
REPs Facility ID: F001213

Date of Issue: 2024-01-30

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