

CERTIFICAT

CERTIFICADO

CERTИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Italia

CERTIFICATO

Nr. 50 100 8125 Rev.010

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF**Delta Med S.p.A.**

SEDE LEGALE E OPERATIVA: / REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA GUIDO ROSSA 20
IT - 46019 VIADANA (MN)**

SEDE OPERATIVA: / OPERATIONAL SITE:

VEDERE **ALLEGATO 1** / SEE **ANNEX 1**È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF**UNI EN ISO 9001:2015**QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione, produzione, vendita e distribuzione di dispositivi medici sterili: set per infusione, cateteri venosi e arteriosi, aghi epicranici, aghi oftalmici, dispositivi medici per uso veterinario e relativi accessori. Produzione e vendita di custom pack per diagnosi e chirurgia, dispositivi di protezione individuale sterili e non sterili e dispositivi medici in tessuto-non tessuto per campo operatorio. Distribuzione e vendita di dispositivi medici e kit: cateteri intravenosi e arteriosi, cerotti, pompe elastomeriche. Produzione conto terzi di dispositivi medici in materiale plastico (IAF 14, 04, 17)

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 (IAF 14, 04, 17)

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: **2024-05-08**Al / To: **2027-05-07**

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements
Francesco ScarlataDirettore Divisione Business Assurance
Business Assurance Division ManagerData emissione /
Issuing Date**2024-02-26****PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2008-11-01**DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2024-05-07
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2024-05-07

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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ALLEGATO 1 AL CERTIFICATO NR 50 100 8125 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 8125 Rev.010
pagina 1 di 1 / page 1 of 1

IL CERTIFICATO NR 50 100 8125 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 8125 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

Delta Med S.p.A.

VIA EMILIO SEGRE' 6
IT - 42041 SORBOLO A LEVANTE DI BRESCELLO (RE)

Produzione di dispositivi medici sterili: cateteri venosi e arteriosi e relativi accessori (IAF 14)

Production of sterile medical devices: intravenous and arterial catheters and related accessories (IAF 14)



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Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

2024-02-26

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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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MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
240647-2017-AE-ITA-ACCREDIA

Initial certification date:
15 June 2017

Valid:
16 June 2023 – 15 June 2026

This is to certify that the management system of

DELTA MED S.p.A.

Via Guido Rossa, 20 - 46019 Viadana (MN) - Italy

has been found to conform to the Environmental Management System standard:
ISO 14001:2015

This certificate is valid for the following scope:

Design and development, manufacturing of sterile medical devices: infusion sets, arterial and intravenous catheters, epicranial needles, ophthalmic needles and related accessories through flaring, cutting, washing, assembling, gluing and packaging phases. Manufacturing of systems and kit for operating theatre and plastic medical devices upon customer's specification through assembling and packaging phases. Manufacturing of sterile and not sterile medical devices in nonwoven and PPE through cutting and packaging phases. Placing on the market of sterile and medical devices such as intravenous catheters and dressing. Trade of infusion sets and elastomeric pumps. (IAF 19, 29)

Evaluated according to the requirements of Technical Regulations RT-09

Place and date:
Vimercate (MB), 22 May 2023



SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F

EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento
SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF
per gli schemi di accreditamento SGQ, SGA, SSI, FSM
e PRD e di MRA ILAC per gli schemi di accreditamento
LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) -
Italy



Claudia Baroncini
Management Representative