



Certificate

No. Q5 106258 0001 Rev. 01

Holder of Certificate: **F.L. Medical s.r.l. Unipersonale**
Via Enrico Mattei 20
Torreglia (PD)
35038
ITALY

Certification Mark:



Scope of Certificate: Design and development, production and distribution of in vitro diagnostic sterile and non-sterile blood collection tubes and devices for sample analysis and urine collection containers and faeces collection devices. Sales of medical device containers for clinical use.

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 106258 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_106258_0001_Rev.01)

Report No.: ITA2095955

Valid from: 2023-10-14

Valid until: 2026-10-13

Date, 2023-09-18



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **F.L. Medical s.r.l. Unipersonale**
Via Enrico Mattei 20, Torreglia (PD), 35038, ITALY

Design and development, production and distribution of in vitro diagnostic sterile and non-sterile blood collection tubes and devices for sample analysis and urine collection containers and faeces collection devices. Sales of medical device containers for clinical use.

F.L. MEDICAL S.r.l. Unipersonale
Via Monte Solone 31, 35038 Torreglia (PD) PD, ITALY

Warehousing of in vitro diagnostic sterile and non-sterile blood collection tubes and devices for sample analysis and urine collection containers and faeces collection devices. Warehousing of medical device containers for clinical use.

/

CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Italia

CERTIFICATO

Nr. 50 100 15861 Rev.001

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

F.L. MEDICAL S.r.l. Unipersonale

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA ENRICO MATTEI 20
IT - 35038 TORREGLIA (PD)**

SEDE OPERATIVA:
OPERATIONAL SITE:

**VIA MONTE SOLONE 31
IT - 35038 TORREGLIA (PD)**

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

Produzione e commercializzazione di dispositivi medici sterili e non sterili per diagnosi in vitro e contenitori per uso clinico (IAF 14)

Production and sale of sterile and non-sterile medical devices for in vitro diagnosis and clinical use containers (IAF 14)



SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

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

Francesco Scarlata

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / Validity

Dal / From: **2023-09-30**

Al / To: **2026-09-29**

Data emissione /
Issuing Date

2023-09-18

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2020-09-30

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2023-09-29

EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2023-09-29

"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"