

CERTIFICATO n. **13165**
CERTIFICATE No

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

F.L. MEDICAL SRL UNIPERSONALE

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.

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

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

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

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

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e vendita di dispositivi medici sterili e non sterili per diagnosi in vitro e di contenitori ad uso clinico.

Production and sale of sterile and non-sterile medical devices for in vitro diagnosis and clinical use containers.

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE **11/11/2008**
FIRST ISSUE
DATA DELIBERA **24/09/2020**
DECISION DATE
DATA SCADENZA **19/10/2023**
EXPIRY DATE
EMISSIONE CORRENTE **24/09/2020**
ISSUE DATE



CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

F.L. MEDICAL SRL UNIPERSONALE

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

for the following scope

Production and sale of sterile and non-sterile medical devices for in vitro diagnosis and clinical use containers.

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2016

Issued on: **2020-09-24**

First issued on: **2008-11-11**

Expires on: **2023-10-19**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration number: **IT-55625**



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

IQNet Partners*:

AENOR *Spain* AFNOR *Certification France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS *Holding GmbH Germany* EAGLE *Certification Group USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta *Sertifiointi Oy Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko *AS Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality *Austria Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS *International Malaysia* SQS *Switzerland* SRAC *Romania* TEST *St Petersburg Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CERTIFICATO n°
CERTIFICATE n° **3283**

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SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

F.L. MEDICAL SRL UNIPERSONALE

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

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

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

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

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI EN ISO 9001:2015

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

SETTORE CODE **IAF 14**

Produzione e vendita di dispositivi medici sterili e non sterili per diagnosi in vitro.
Gestione della produzione e vendita di contenitori non sterili ad uso clinico.

*Production and sale of sterile and non-sterile medical devices for in vitro diagnosis.
Management of production and sales of non sterile containers for clinical use .*

IL PRESENTE CERTIFICATO È SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE FIRST ISSUE	24/09/2001
DATA DELIBERA DECISION DATE	05/10/2021
DATA SCADENZA EXPIRY DATE	06/10/2024
EMISSIONE CORRENTE CURRENT ISSUE	05/10/2021



CERTIQUALITY S.r.l. IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



SGQ n. 008 A

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



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

F.L. MEDICAL SRL UNIPERSONALE

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

for the following scope

Production and sale of sterile and non-sterile medical devices for in vitro diagnosis. Management of production and sales of non sterile containers for clinical use .

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard
ISO 9001:2015

Issued on: 05/10/2021
First issued on: 24/09/2001
Expires on: 06/10/2024

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration number: IT- 15999

Cisq Certificate: 3283



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland NYCE-
SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

DECLARATION OF CONFORMITY

F.L. MEDICAL s.r.l. Unipersonale
Having headquarters in
Via Enrico Mattei, 20
35038 TORREGLIA (PADOVA)
ITALY

manufacturer of disposable plastic wares for analysis laboratory, declares on its responsibility that the IVD below indicated meet the essential requirements of annex 3 according to art. 9 of directive 98/79/EEC:

Containers for biological liquids
Sterile containers for biological liquids
Petri dishes, spreaders and inoculation loops
Sample cups and cuvettes for autoanalyzer
Tips for pipettes
Pasteur pipettes
Sterile Pasteur pipettes
ESR systems
Test tubes for biological liquids collection
Sterile test tubes for biological liquids collection
Test tubes for blood collection
Vacuum test tubes for blood collection sterile

The technical documentation is located in our facilities under the responsibility of the quality assurance manager.

Torreglia, 07.09.2021

F.L. Medical s.r.l.
Riccardo Fiore

A handwritten signature in black ink, appearing to read 'R. Fiore', written in a cursive style.