

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 *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

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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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F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
Tel. +39 049 5211475 / +39 049 5212835 - Fax +39 049 5212566
e-mail: info@flmedical.com - web site: www.flmedical.com
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', is written below the printed name.

SCHEDA TECNICA / TECHNICAL INFORMATION

ARTICOLO / ITEM 21402

PROMED ® PR. 30x115 mm 50 ml CONICA IN POLIPROPILENE TAPPO ROSSO
 A VITE GRADUATA STERILE
 PROMED ® TEST TUBE 30x115 mm 50 ml CONICAL IN POLYPROPYLENE RED
 SCREW CAP GRADUATED STERILE

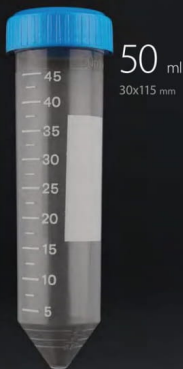
Produttore / Manufacturer	F.L. MEDICAL s.r.l.
Indirizzo / Address	Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy

1. INFORMAZIONI TECNICHE / TECHNICAL INFORMATION:	
CODICE ARTICOLO / CODE:	21402
CAPACITA' / CAPACITY:	50 ml
MATERIALE PROVETTA / TUBE MATERIAL:	Polipropilene / Polypropylene
MATERIALE TAPPO / CAP MATERIAL:	Polietilene / Polyethylene
ASPETTO / APPEARANCE:	Conica / Conical
MISURE ESTERNE / OUTSIDE SIZES:	\varnothing inferiore / \varnothing lower: N.A. \varnothing superiore / \varnothing higher: 34,5 mm Altezza senza tappo / Height without cap: 115 mm Altezza con tappo / Height with cap: 128 mm
COLORE PROVETTA / TUBE COLOUR:	Neutro, trasparente / Neutral, transparent
COLORE TAPPO / CAP COLOUR:	Rosso / Red
ALTRE CARATTERISTICHE / OTHER CHARACTERISTICS:	Graduazione a / Graduated at: 5-7,5-10-15-20-25-30-35-40-45-50 ml
2. STERILIZZAZIONE / STERILIZATION:	
Raggi Beta/ Beta Rays	
3. QUANTITA' CONFEZIONE / BOX QUANTITY:	
Confezione da 500 pz / 500 pcs. per box	
4. QUANTITA' INTERNA / INNER QUANTITY:	
Articoli sfusi / Bulk items	
5. VOLUME SCATOLA / BOX VOLUME:	
mc / cbm: 0,101	
Misure scatola / box sizes: 44,5 x 44 x 51,7 cm	
6. PESO SCATOLA / BOX WEIGHT:	
Peso lordo / Gross weight: 8,4 Kg	
7. INFORMAZIONI AGGIUNTIVE / ADDITIONAL INFORMATION:	
Prodotto IVD, marcato CE / IVD item, CE marked	
8. STOCCAGGIO / STORAGE:	
Non porre a contatto o nelle vicinanze di fiamme, non disperdere il prodotto nell'ambiente in quanto non biodegradabile / Do not expose or leave near open flames, do not leave the product around as it is not biodegradable.	



Centrifuge test tubes

Tubos para centrifuga / Tubes centrifugeable / Provette per centrifuga



21401

test tube conical
tubo cónico / tube conique / provetta conica

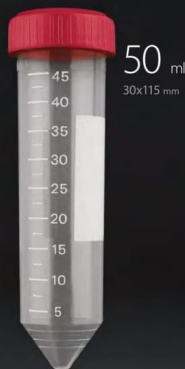
graduated
graduado / gradué / graduata

with writing area
banda mate / surface d'écriture / superficie di scrittura

PP polypropylene
polipropileno / polypropylène / polipropilene

screw cap
tapa de rosca / bouchon à vis / tappo a vite

light blue
azul / blue clair / azzurro



21402

test tube conical
tubo cónico / tube conique / provetta conica

graduated
graduado / gradué / graduata

with writing area
banda mate / surface d'écriture / superficie di scrittura

sterile
estéril / stérile / sterile

PP polypropylene
polipropileno / polypropylène / polipropilene

screw cap
tapa de rosca / bouchon à vis / tappo a vite

red
rojo / rouge / rosso



50 ml
30x115 mm



21400

test tube conical
tubo cónico / tube conique / provetta conica

graduated
graduado / gradué / graduata

with writing area
banda mate / surface d'écriture / superficie di scrittura

sterile
estéril / stérile / sterile

individually wrapped
embalado individualmente / sachet unitaire / confezione singola

PP polypropylene
polipropileno / polypropylène / polipropilene

screw cap
tapa de rosca / bouchon à vis / tappo a vite

red
rojo / rouge / rosso



Serum separator tubes

Tubos separadores de suero / Tubes avec gel séparateur / Provette con separatore di siero

separmed tech®

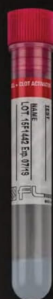


silicone coated interior

interior recubierto de silicona / silicone à l'intérieur / siliconata internamente



13x75 mm



22744

test tube with gel separator and clot activator silicone coated interior

tubo con gel separador y activador de la coagulación interior recubierto de silicona / tube avec gel séparateur et activateur de la coagulation silicone à l'intérieur / provetta con gel separatore e acceleratore siliconata internamente



polypropylene

polipropileno / polypropylène / polipropilene

with label

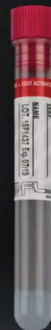
con etiqueta / avec étiquette / con etichetta



red

rojo / rouge / rosso

12x86 mm



22734

test tube with gel separator and clot activator silicone coated interior

tubo con gel separador y activador de la coagulación interior recubierto de silicona / tube avec gel séparateur et activateur de la coagulation silicone à l'intérieur / provetta con gel separatore e acceleratore siliconata internamente



polypropylene

polipropileno / polypropylène / polipropilene

with label

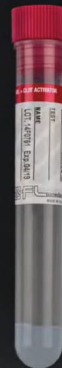
con etiqueta / avec étiquette / con etichetta



red

rojo / rouge / rosso

16x100 mm



22702

test tube with gel separator and clot activator silicone coated interior

tubo con gel separador y activador de la coagulación interior recubierto de silicona / tube avec gel séparateur et activateur de la coagulation silicone à l'intérieur / provetta con gel separatore e acceleratore siliconata internamente



polypropylene

polipropileno / polypropylène / polipropilene

with label

con etiqueta / avec étiquette / con etichetta



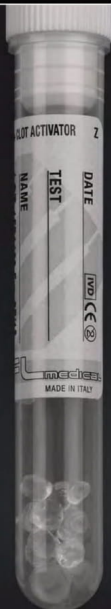
red

rojo / rouge / rosso



Serum separator tubes

Tubos separadores de suero / Tubes avec gel séparateur / Provette con separatore di siero



separmed tech®

13x75 mm



+ silicone coated interior
Interior recubierto de silicona / *silicone à l'intérieur* / siliconata internamente

22634

test tube with granules separators silicone coated interior
tubo con gránulos separadores interior recubierto de silicona / *tube avec granules séparateurs silicone à l'intérieur* / provetta con granuli separatori siliconata internamente

PP polypropylene
polipropileno / *polypropylene* / polipropilene

with label
con etichetta / *avec étiquette* / con etichetta

white
blanco / *blanc* / bianco

12x86 mm



22626

test tube with granules separators silicone coated interior
tubo con gránulos separadores interior recubierto de silicona / *tube avec granules séparateurs silicone à l'intérieur* / provetta con granuli separatori siliconata internamente

PP polypropylene
polipropileno / *polypropylene* / polipropilene

with label
con etichetta / *avec étiquette* / con etichetta

white
blanco / *blanc* / bianco

16x100 mm



22602

test tube with granules separators silicone coated interior
tubo con gránulos separadores interior recubierto de silicona / *tube avec granules séparateurs silicone à l'intérieur* / provetta con granuli separatori siliconata internamente

PP polypropylene
polipropileno / *polypropylene* / polipropilene

with label
con etichetta / *avec étiquette* / con etichetta

white
blanco / *blanc* / bianco



Urine containers 120 ml

Frascos 120 ml para orina / Pots 120 ml pour urine / Contenitori urina 120 ml

120 ml

120 ml



25030

25031

25033

25034

25036



urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface d'écriture / contenitore per urina con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene

with screw cap apart
con tapón no roscado / avec bouchon à vis no jointé / con tappo a vite a parte

white
blanco / blanc / bianco



urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface d'écriture / contenitore per urina con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene

with screw cap apart
con tapón no roscado / avec bouchon à vis no jointé / con tappo a vite a parte

red
rojo / rouge / rosso



urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface d'écriture / contenitore per urina con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene

with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

white
blanco / blanc / bianco



urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface d'écriture / contenitore per urina con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene

with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

red
rojo / rouge / rosso



urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface d'écriture / contenitore per urina con superficie di scrittura



sterile
estéril / stérile / sterile

with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

red
rojo / rouge / rosso



Faeces containers 30 ml

Frasco 30 ml para heces / Pot 30 ml pour selles / Contenitori feci 30 ml



30 ml



30 ml



25130

25131

25133

25134

25136



faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface d'écriture / contenitore per feci con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene



with screw cap apart
con tapón no roscado / avec bouchon à vis no jointé / con tappo a vite a parte

white
blanco / blanc / bianco



faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface d'écriture / contenitore per feci con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene



with screw cap apart
con tapón no roscado / avec bouchon à vis no jointé / con tappo a vite a parte

red
rojo / rouge / rosso



faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface d'écriture / contenitore per feci con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene



with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

white
blanco / blanc / bianco



faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface d'écriture / contenitore per feci con superficie di scrittura



polypropylene
polipropileno / polypropylène / polipropilene



with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

red
rojo / rouge / rosso



faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface d'écriture / contenitore per feci con superficie di scrittura



sterile
estéril / stérile / sterile



polypropylene
polipropileno / polypropylène / polipropilene



with screw cap
con tapón roscado / avec bouchon à vis jointé / con tappo a vite

red
rojo / rouge / rosso