

F.L. MEDICAL s.r.l.
Via San Pietro Montagnon, 11/1 - 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

Torreglia, 18.01.2010

TO WHOM IT MAY CONCERN

Our. ref. n° 004Y/10

Object: authorization letter

The company

F.L. Medical s.r.l.

with headquarter in

**Via San Pietro Montagnon, 11/1
35038 TORREGLIA
PADOVA
ITALY**

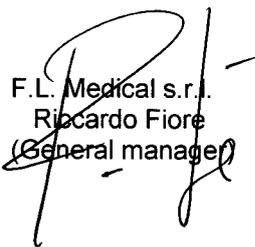
declares that this letter acknowledges that

**ECOCHIMIE Ltd.
5/1, Cuza Voda str.
2060MD, Chisinau,
Republic of Moldova
Tel/fax +373(22)-52-34-32, 52-34-22
infoecochimie@gmail.com
info@ecochimie.md
www.ecochimie.md**

is our authorized distributor for the complete disposable labware product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of F.L. MEDICAL s.r.l. products to their customers in his area and to participate in tenders on behalf of F.L. MEDICAL s.r.l.

F.L. Medical s.r.l.
Riccardo Fiore
(General manager)





F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
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e-mail: info@flmedical.com - web site: www.flmedical.com
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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, 02.04.2014

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

A handwritten signature in black ink, appearing to read 'R. Fiore', is positioned below the printed name.



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)**

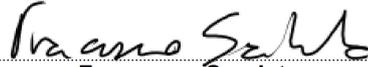
È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

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)

 L'ENTE ITALIANO DI ACCREDITAMENTO 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.	Validità /Validity Dal / From: 2023-09-30 Al / To: 2026-09-29
	 Francesco Scariata Direttore Divisione Business Assurance Business Assurance Division Manager	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"



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

No. Q5 106258 0001 Rev. 01

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.

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