



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

Torreglia, 31.03.2017

Our. ref. n° 035Y/17

Object: authorization letter

TO WHOM IT MAY CONCERN

The company

F.L. Medical s.r.l.

with headquarter in

Via Enrico Mattei, 20
35038 TORREGLIA
PADOVA
ITALY

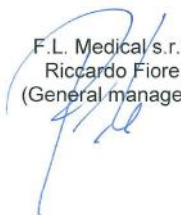
declares that this letter acknowledges that

Ecochimie SRL

with headquarter in

Cuza Voda str. 5/1, Fl. 4 office 403
2060 Chisinau
Moldavia

is our authorized distributor till 31.12.2019 in Moldavia for the laboratory products manufactured and distributed by us and is entitled to represent, distribute, import and register our products.


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



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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





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


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



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

Manufacturing and sale of disposable plasticware for analysis laboratories and medical swabs for biological samples collection

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard

ISO 9001:2015

Issued on: **2018-09-12**
First issued on: **2001-09-24**
Expires on: **2021-10-07**

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**



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
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 FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico 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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* 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. **3283**
CERTIFICATE No

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 S. PIETRO MONTAGNON 11/1
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 COMPLES WITH THE FOLLOWING STANDARD

UNI EN ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES **SETTORE CODE IAF 14**

Produzione e vendita di articoli monouso per laboratorio di analisi e di tamponi medicali per il prelievo di campioni biologici.

Manufacturing and sale of disposable plasticware for analysis laboratories and medical swabs for biological samples collection



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 **24/09/2001**
FIRST ISSUE
DATA DELIBERA **12/09/2018**
DECISION DATE
DATA SCADENZA **07/10/2021**
EXPIRY DATE
EMISSIONE CORRENTE **12/09/2018**
ISSUE DATE

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



MEMBRO DEGLI ACCORDI DI MUTUO RICONOSCIMENTO EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CONT ED 08 010618

CISQ is a member of



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.

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.



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.