



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](mailto:info@flmedical.com) - web site: [www.flmedical.com](http://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

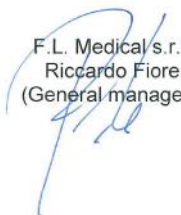
declares that this letter acknowledges that

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







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  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://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



CON ED 08 010618

MEMBRO DEGLI ACCORDI DI MUTUO  
RICONOSCIMENTO EA, IAF e ILAC  
SIGNATARY OF EA, IAF and ILAC Mutual  
Recognition Agreements

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](http://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](http://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

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 13485:2016**

Issued on: **2018-09-12**  
First issued on: **2008-11-11**  
Expires on: **2020-10-20**

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. 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 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  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



CERTIFICATO n. **13165**  
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 COMPLIES WITH THE FOLLOWING STANDARD

## UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

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 **11/11/2008**  
FIRST ISSUE  
DATA DELIBERA **12/09/2018**  
DECISION DATE  
DATA SCADENZA **20/10/2020**  
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  
SIGNATARY OF EA, IAF and ILAC MUTUAL RECOGNITION AGREEMENTS



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 39 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](http://www.certiquality.it)

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



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**ORGANISMO NOTIFICATO N° 0546**  
*NOTIFIED BODY N° 0546*

**APPROVAZIONE DEL SISTEMA DI QUALITA' ATTUATO DA**  
*APPROVAL OF THE QUALITY SYSTEM OPERATED BY*

**F.L. MEDICAL SRL UNIPERSONALE**

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

UNITA' OPERATIVE  
OPERATING SITES

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

PER I SEGUENTI TIPI / FAMIGLIE DI PRODOTTI  
*FOR THE FOLLOWING TYPES / CLASSES OF PRODUCTS*

**Tamponi medicali e applicatori, sterili e non, per prelievo campioni  
e analisi microbiologica, con o senza terreno di trasporto**

*Medical swabs and applicators, sterile and not sterile, for sample collection  
and microbiology investigation, with or without transport medium*

**Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema garanzia qualità**

*Certiquality S.r.l., Notified Body n° 0546, certifies that the quality assurance system*

**è conforme ai requisiti della Direttiva 93/42 CEE, Allegato V**

*is in compliance with the requirements of Council Directive 93/42/CEE, Annex*

CERTIFICATO N. **14967/1**  
CERTIFICATE N.

PRIMA EMISSIONE  
FIRST ISSUE 27/10/2009

EMISSIONE CORRENTE  
CURRENT ISSUE 10/04/2017

DATA DI SCADENZA  
EXPIRY DATE 21/10/2019

*Emilio...*

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ

Via Gaetano Giardino 4 - 20123 Milano - tel. 02 8069171 - fax 02 86465295 - [certiquality@certiquality.it](mailto:certiquality@certiquality.it) - [www.certiquality.it](http://www.certiquality.it)

