

CERTIFICATO n°
CERTIFICATE n° **58403**

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

EUROFINS REGULATORY & CONSULTANCY SERVICES ITALY S.R.L.

IT - 20055 VIMODRONE (MI) - VIA BRUNO BUOZZI 2

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 20055 VIMODRONE (MI) - VIA BRUNO BUOZZI 2

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 13485:2021

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione e sviluppo di protocolli per la caratterizzazione chimico-fisica e microbiologica e la valutazione biologica di dispositivi medici, la convalida di processi critici (lavaggio, disinfezione, sterilizzazione e confezionamento) e di siti di produzione nel settore biomedicale. Consulenza per la realizzazione di Documentazione Tecnica. Progettazione ed erogazione di servizi di formazione riferita a dispositivi medici. Progettazione ed erogazione di servizi di usabilità nel settore dispositivi medici.

Design and development of protocols for the chemical-physical and microbiological characterization and biological evaluation of medical devices, the validation of critical processes (cleaning, disinfection, sterilization and packaging) and of production sites in the biomedical sector.

Consulting services for editing of Technical Documentation. Design and provision of training services related to medical devices. Design and provision of services for usability evaluation related to medical devices.

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
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EXPIRY DATE 26/07/2026

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CURRENT ISSUE 10/07/2025



Marco Martinelli
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.



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

Certificate

CISQ/CERTIQUALITY S.r.l. has issued an IQNET recognized certificate that the organization:

EUROFINS REGULATORY & CONSULTANCY SERVICES ITALY S.R.L.

IT-20055 VIMODRONE (MI) - VIA BRUNO BUOZZI 2

has implemented and maintains a/an
Quality Management System

for the following scope:

Design and development of protocols for the chemical-physical and microbiological characterization and biological evaluation of medical devices, the validation of critical processes (cleaning, disinfection, sterilization and packaging) and of production sites in the biomedical sector. Consulting services for editing of Technical Documentation. Design and provision of training services related to medical devices. Design and provision of services for usability evaluation related to medical devices.

which fulfils the requirements of the following **standard**:

ISO 13485:2016

Issued on: 10/07/2025
First issued on: 27/07/2023
Expires on: 26/07/2026

Registration Number: **IT- 137870 - 58403**


Alex Stoichitoiu
President of IQNET


Mario Romersi
President of CISQ



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

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