

CERTIFICATO N. **1044.2024**
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

VYGON ITALIA SRL

VIALE DELL'INDUSTRIA 60/1A - 35129 PADOVA (PD) Italy
UNITA' OPERATIVE/OPERATIVE UNITS
VIALE DELL'INDUSTRIA 60/1A - 35129 PADOVA (PD) Italy
VIALE NUOVA ZELANDA 8 - 35100 PADOVA (PD) Italy

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Distribuzione di dispositivi medici e accessori per medicina, oncologia, chirurgia, cardiologia, emodialisi, anestesia, terapia intensiva, terapia del dolore e terapia d'urgenza. Gestione della produzione e distribuzione di sistemi e kit procedurali per medicina, oncologia, chirurgia, cardiologia, emodialisi, anestesia, terapia intensiva, terapia del dolore e terapia d'urgenza. Gestione della progettazione, dello sviluppo, della produzione, assistenza tecnica e distribuzione di elettro-neuro stimolatori.

Distribution of medical devices and accessories for medicine, oncology, surgery, cardiology, hemodialysis, anesthesia, intensive care, pain therapy and emergency therapy. Management of the production and distribution of systems and procedure kits for medicine, oncology, surgery, cardiology, hemodialysis, anesthesia, intensive care, pain therapy and emergency therapy. Management of the design, development, production, technical assistance and distribution of electro-neuro stimulators.

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

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 CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	04/03/2023	17/01/2025	03/03/2026



IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro organismo
First certification date is related to issue date of another Certification Body



MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years



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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/IMQ has issued an IQNET recognized certificate that the organization:

VYGON ITALIA SRL

VIALE DELL'INDUSTRIA 60/1A - 35129 PADOVA (PD) Italy

VIALE NUOVA ZELANDA 8 - 35100 PADOVA (PD) Italy

has implemented and maintains a
Quality Management System

for the following scope:

Distribution of medical devices and accessories for medicine, oncology, surgery, cardiology, hemodialysis, anesthesia, intensive care, pain therapy and emergency therapy. Management of the production and distribution of systems and procedure kits for medicine, oncology, surgery, cardiology, hemodialysis, anesthesia, intensive care, pain therapy and emergency therapy. Management of the design, development, production, technical assistance and distribution of electro-neuro stimulators. Marketing of medical devices.

which fulfills the requirements of the following standard:

ISO 13485:2016

Issued on: **2025/01/17**

Expires on: **2026/03/03**

Registration Number:



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.

IQNET Members*:

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Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
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SIRIM QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com