Il certificato è stato rilasciato in precedenza da un altro CAB.
The certificate has been issued previously by another CAB.

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CERTIFICATO N. **ICIM-13485-050205-02**
CERTIFICATE No.

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

MED-EUROPE EUROPEAN MEDICAL SUPPLIES S.R.L.

VIA NAZARIO SAURO, 29 40121 BOLOGNA BO IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione e immissione in commercio dispositivi medici sterili e non per il settore chirurgico e non: dispositivi non attivi e non impiantabili, impianti funzionali non attivi, sonde per il monitoraggio di parametri fisiologici.

Design, manufacture and place on the market of sterile and non-sterile medical devices for the surgical field and non-surgical field: non-active non-implantable devices, non-active functional implants and probes for monitoring physiological parameters.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
15/11/2019	29/10/2026	14/11/2028

Federico Pasqui
Rappresentante Direzione / *Management Representative*

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

IS-CSG-0274-UCM-01-IT

MANAGEMENT SYSTEM CERTIFICATION ACCREDIA

00012

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www.cisq.com

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Il certificato è stato rilasciato in precedenza da un altro CAB.
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Allegato al CERTIFICATO N. **ICIM-13485-050205-02**
Attachment to CERTIFICATE No.

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

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VIA NAZARIO SAURO, 29 40121 BOLOGNA BO IT - Italia

UNITÀ OPERATIVE / *OPERATIVE UNITS*

VIA GRAMSCI, 9 40018 SAN PIETRO IN CASALE BO IT - Italia	Amministrazione, Qualità ed Affari Regolatori, Progettazione, Acquisti.	Administration, Quality & Regulatory Affairs, Design and Development, Purchasing.
VIA GRAMSCI, 1 40018 SAN PIETRO IN CASALE BO IT - Italia	Produzione, camere bianche, magazzino.	Production, Cleanroom Facilities, and Warehouse.
VIA GRAMSCI, 1D 40018 SAN PIETRO IN CASALE BO IT - Italia	Produzione, camere bianche, magazzino.	Production, Cleanroom Facilities, and Warehouse.
VIA GRAMSCI, 3 40018 SAN PIETRO IN CASALE BO IT - Italia	Produzione, camere bianche, magazzino.	Production, Cleanroom Facilities, and Warehouse.
VIA GRAMSCI, 5 40018 SAN PIETRO IN CASALE BO IT - Italia	Produzione, camere bianche, magazzino.	Production, Cleanroom Facilities, and Warehouse.

MANAGEMENT SYSTEM CERTIFICATION ACCREDIA
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Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

MED-EUROPE EUROPEAN MEDICAL SUPPLIES S.R.L.

VIA GRAMSCI, 9 40018 SAN PIETRO IN CASALE BO IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Design, manufacture and place on the market of sterile and non-sterile medical devices for the surgical field and non-surgical field: non-active non-implantable devices, non-active functional implants and probes for monitoring physiological parameters.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2026-10-29**
First issued on:	**2019-11-15**
Expires on:	**2028-11-14**

Registration Number:

IT-142779 ICIM-13485-050205-02

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

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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Annex 1 to IQNET Certificate Number:

IT-142779 ICIM-13485-050205-02

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VIA GRAMSCI, 9 40018 SAN PIETRO IN CASALE BO IT - Italia

List of additional locations:

VIA GRAMSCI, 1 40018 SAN PIETRO IN CASALE BO IT - Italia
VIA GRAMSCI, 1D 40018 SAN PIETRO IN CASALE BO IT - Italia
VIA GRAMSCI, 3 40018 SAN PIETRO IN CASALE BO IT - Italia
VIA GRAMSCI, 5 40018 SAN PIETRO IN CASALE BO IT - Italia

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