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ICIM

CERTIFICATO N. **ICIM-13485-009995-04**

CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

STUDIO AMBIENTE S.R.L.

VIA MONTE BALDO 4 37062 DOSSOBUONO VR IT - Italia

UNITÀ OPERATIVA / *OPERATIVE UNIT*

VIA MONTE BALDO, 4 37062 DOSSOBUONO VR IT - Italia

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 ed erogazione di attività formative per aziende del settore biomedicale e per Organismi Notificati su aspetti tecnico-normativi e regolatori. Erogazione di consulenza per aziende su dispositivi medici. Analisi di laboratorio microbiologiche e fisiche su dispositivi medici. Sviluppo di protocolli di validazione per processi critici quali sterilizzazione, disinfezione, confezionamento, pulizia, verifica del sistema di barriera sterile e shelf life su dispositivi e prodotti medicali. Prove di efficienza per dispositivi medici disinfettanti. Validazione ambienti a contaminazione controllata con prove fisiche, microbiologiche e particellari.

Design and provision of training activities for companies in the biomedical sector and for Notified Bodies on technical-standard and regulatory aspects. Provision of consultancy for companies on medical devices. Microbiological and physical laboratory analyses in the biomedical, medical devices. Development of validation protocols for critical processes such as sterilization, disinfection, packaging, cleaning, sterile barrier system verification and shelf life on medical devices and medical products. Efficacy tests for disinfectants medical devices. Validation of controlled contamination environments with physical, microbiological and particle tests.

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*
14/10/2013	20/09/2026	19/09/2029

Federico Pasqui

Rappresentante Direzione / *Management Representative*

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)

www.icim.it

MANAGEMENT SYSTEM CERTIFICATION ACCREDIA

00012

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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.

IQNET

Building trust together.

Certificate

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

STUDIO AMBIENTE S.R.L.

VIA MONTE BALDO, 4 37062 DOSSOBUONO VR IT - Italia

has implemented and maintains a/an

Quality Management System

for the following scope:

Design and provision of training activities for companies in the biomedical sector and for Notified Bodies on technical-standard and regulatory aspects. Provision of consultancy for companies on medical devices. Microbiological and physical laboratory analyses in the biomedical, medical devices. Development of validation protocols for critical processes such as sterilization, disinfection, packaging, cleaning, sterile barrier system verification and shelf life on medical devices and medical products. Efficacy tests for disinfectants medical devices. Validation of controlled contamination environments with physical, microbiological and particle tests.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2026-09-20**
First issued on:	**2013-10-14**
Expires on:	**2029-09-19**

Registration Number:

IT-129947 ICIM-13485-009995-04

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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