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CERTIFICATO N.  
CERTIFICATE No.

ICIM-13485-009995-02

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.

UNITÀ OPERATIVA / OPERATIVE UNIT

Via Monte Baldo, 4 37062 Dossobuono di Villafranca 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

Erogazione di servizi di consulenza su aspetti tecnico-normativi e regolatori per il settore biomedicale e in ambito dispositivi medici. Erogazione di attività formative per aziende del settore biomedicale e per Organismi Notificati su aspetti tecnico-normativi e regolatori. 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 medici. Prove di efficacia per dispositivi medici disinfettanti. Validazione di ambienti a contaminazione controllata con prove fisiche, microbiologiche e particellari.

*Provision of consultancy services on technical-standard and regulatory aspects for the biomedical sector and on medical devices. Provision of training activities for companies in the biomedical sector and for Notified Bodies on technical-standard and regulatory aspects. Microbiological and physical laboratory analyses on 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. Efficacy tests for disinfectant 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.

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SGQ N° 004 A



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

## **STUDIO AMBIENTE S.R.L.**

**Via Monte Baldo, 4 37062 Dossobuono di Villafranca IT - Italia**

has implemented and maintains a/an

### **Quality Management System**

for the following scope:

**Provision of consultancy services on technical-standard and regulatory aspects for the biomedical sector and on medical devices. Provision of training activities for companies in the biomedical sector and for Notified Bodies on technical-standard and regulatory aspects. Microbiological and physical laboratory analyses on 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. Efficacy tests for disinfectant 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: **2023-09-20**  
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**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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