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CERTIFICATO N.
CERTIFICATE No.

ICIM-9001-009994-02

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 / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 34 - 37

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 e prodotti cosmetici ed industriali. Analisi di laboratorio microbiologiche e fisiche nei settori biomedicale, dispositivi medici, farmaceutico ed industriale. 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 efficacia per disinfettanti e Presidi Medico Chirurgici. Validazione ambienti a contaminazione controllata con prove fisiche, microbiologiche e particellari.

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, cosmetic and industrial products. Microbiological and physical laboratory analyses in the biomedical, medical devices, pharmaceutical and industrial sectors. Development of validation protocols for critical processes such as sterilization, disinfection, packaging, cleaning, sterile barrier system verification and shelf life on medical devices and products. Efficacy tests for disinfectants and biocidal products. 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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Rappresentante Direzione / Management Representative

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A



www.cisq.com

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 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, cosmetic and industrial products. Microbiological and physical laboratory analyses in the biomedical, medical devices, pharmaceutical and industrial sectors. Development of validation protocols for critical processes such as sterilization, disinfection, packaging, cleaning, sterile barrier system verification and shelf life on medical devices and products. Efficacy tests for disinfectants and biocidal products. Validation of controlled contamination environments with physical, microbiological and particle tests.

which fulfils the requirements of the following standard:

ISO 9001:2015

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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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