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CERTIFICATO N.
CERTIFICATE No.

ICIM-13485-051919-00

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

ESTOR SPA

UNITÀ OPERATIVA / OPERATIVE UNIT

VIA NEWTON, 12 20016 PERO MI 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

Gestione della fabbricazione, immissione in commercio e assistenza tecnica di dispositivi medici per la circolazione extra-corporea. Commercializzazione e assistenza tecnica di dispositivi medici e diagnostici in vitro (IVD).

Manufacturing management, placing on the market and servicing of medical devices for extra-corporeal circulation. Trading and servicing of medical devices and in vitro diagnostic devices.

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
FIRST ISSUE
23/01/2026

EMISSIONE CORRENTE
CURRENT ISSUE
23/01/2026

DATA DI SCADENZA
EXPIRING DATE
22/01/2029

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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:

ESTOR SPA

VIA NEWTON, 12 20016 PERO MI IT - Italia

has implemented and maintains a/an

Quality Management System

for the following scope:

Manufacturing management, placing on the market and servicing of medical devices for extra-corporeal circulation. Trading and servicing of medical devices and in vitro diagnostic devices.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2026-01-23**

First issued on: **2026-01-23**

Expires on: **2029-01-22**

Registration Number:

IT-150598 ICIM-13485-051919-00



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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