

CERTIFICATO n° **5999**
CERTIFICATE n°

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

SAPIO LIFE S.R.L.

IT-20900 MONZA (MB) - VIA SILVIO PELLICO 48

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 20069 VAPRIO D'ADDA (MI) - VIA CASCINELLO 2
IT - 20900 MONZA (MB) - VIA SILVIO PELLICO 48

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2021

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

VEDASI ALLEGATO/SEE ANNEX

IL PRESENTE CERTIFICATO È SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE FIRST ISSUE	28/01/2003
DATA DELIBERA DECISION DATE	15/01/2024
DATA SCADENZA EXPIRY DATE	18/01/2027
EMISSIONE CORRENTE CURRENT ISSUE	23/02/2024



CERTIQUALITY S.r.l. IL PRESIDENTE
Via G. Giardino 4 – 20123 MILANO (MI) - ITALY

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX



SGQ n. 008 A

Membro degli Accordi di Mutuo riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC Mutual Recognition Agreements.



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.

ALLEGATO AL CERTIFICATO n°
ANNEX TO CERTIFICATE n°

5999

SAPIO LIFE S.R.L.

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione, fabbricazione, installazione, immissione in commercio e manutenzione di impianti di distribuzione dei gas medicinali e dei gas dispositivo medico e loro miscele, delle relative centrali di alimentazione o produzione, di impianti del vuoto e di impianti di evacuazione dei gas anestetici.

Distribuzione, manutenzione, collaudo, assistenza tecnica, sanitizzazione e immagazzinamento di apparecchiature elettromedicali, di dispositivi medici e di sistemi per ventiloterapia e ossigenoterapia per l'utilizzo ospedaliero e domiciliare.

Progettazione, gestione della produzione, immissione in commercio e distribuzione, in bombole, serbatoi e contenitori criogenici mobili, di gas dispositivi medici per laparoscopia, crioterapia, isteroscopia, endoscopia digestiva, toracoscopia, elettrocoagulazione al plasma e crioconservazione e per la conservazione e crescita di colture cellulari in vitro nell'ambito di terapie cellulari e trapianti sui pazienti e di miscele gassose dispositivi medici per il controllo e la diagnosi della funzionalità polmonare.

Design, manufacturing, installation, marketing and maintenance of pipeline systems for medicinal gases and medical device gases and their mixtures, of the related supply or production units, of pipeline systems for vacuum and of anesthetic gas scavenging disposal systems.

Distribution, maintenance, testing, technical assistance, sanitization and storage of electro-medical equipment, medical devices and ventilation and oxygen therapy systems for hospital and home use.

Design, production management, placing on the market and distribution, in cylinders, tanks and mobile cryogenic containers, of gas medical devices for laparoscopy, cryotherapy, hysteroscopy, digestive endoscopy, thoracoscopy, plasma coagulation and cryopreservation and for the preservation and growth of cultures in vitro cells in the context of cell therapies and transplants on patients and gaseous mixtures medical devices for the control and diagnosis of lung function.

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Via G. Giardino 4 – 20123 MILANO (MI) - ITALY

IL PRESENTE ALLEGATO NON È DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
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Certificate

CISQ/CERTIQUALITY S.r.l. has issued an IQNET recognized certificate that the organization:

SAPIO LIFE S.R.L.

IT-20900 MONZA (MB) - VIA SILVIO PELLICO 48

has implemented and maintains a/an
Quality Management System

for the following scope:
See Annex

which fulfils the requirements of the following **standard**:

ISO 13485:2016

Issued on: 23/02/2024
First issued on: 28/01/2003
Expires on: 18/01/2027

Registration Number: **IT- 24949 - 5999**


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.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SGS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Annex 2 to IQNET Certificate Number

IT- 24949

SAPIO LIFE S.R.L.

Field of scope

Design, manufacturing, installation, marketing and maintenance of pipeline systems for medicinal gases and medical device gases and their mixtures, of the related supply or production units, of pipeline systems for vacuum and of anesthetic gas scavenging disposal systems.

Distribution, maintenance, testing, technical assistance, sanitization and storage of electro-medical equipment, medical devices and ventilation and oxygen therapy systems for hospital and home use.

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