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**CERTIFICATO N.**  
**CERTIFICATE No.**

**DM/08/22**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI  
IT IS HEREBY CERTIFIED THAT THE QUALITY MANAGEMENT SYSTEM OF

**LEDRAGOMMA S.R.L.**

ZONA INDUSTRIALE VIA GIOVANNI DE SIMON S.N.C. 33010 Osoppo (UD) ITA

NELLE SEGUENTI UNITÀ OPERATIVE / IN THE FOLLOWING OPERATIONAL UNITS

ZONA INDUSTRIALE VIA GIOVANNI DE SIMON S.N.C. 33010 Osoppo (UD) ITALIA

Per informazioni sulla validità  
del certificato, visitare il sito  
www.rina.org

For information concerning  
validity of the certificate, you  
can visit the site  
www.rina.org

È CONFORME ALLA NORMA  
IS IN COMPLIANCE WITH THE STANDARD

**EN ISO 13485:2016**

PER I SEGUENTI CAMPI DI ATTIVITÀ / FOR THE FOLLOWING FIELD(S) OF ACTIVITIES

PROGETTAZIONE, SVILUPPO E PRODUZIONE DI DISPOSITIVI MEDICI IN MATERIA PLASTICA NON ATTIVI PER  
FISIOTERAPIA E RIABILITAZIONE.

DESIGN, DEVELOPMENT AND MANUFACTURE OF NON-ACTIVE PLASTIC DEVICES FOR PHYSIOTHERAPY AND  
REHABILITATION.

La validità del presente certificato è subordinata a sorveglianza periodica annuale / semestrale ed al riesame completo del sistema di gestione con periodicità  
triennale

The validity of this certificate is dependent on an annual / six monthly audit and on a complete review, every three years, of the management system

Riferirsi al Manuale della Qualità per i dettagli delle esclusioni ai requisiti della norma

Reference is to be made to the Quality Manual for details regarding the exemptions from the requirements of the standard

L'uso e la validità del presente certificato sono soggetti al rispetto del documento RINA: Regolamento per la certificazione di Sistemi di Gestione Qualità nel settore  
Dispositivi Medici

The use and validity of this certificate are subject to compliance with the RINA document: Rules for the certification of Quality Management Systems in the Medical  
Devices sector

Prima emissione First Issue	<u>21.10.2008</u>	Data decisione di rinnovo Renewal decision date	<u>18.10.2023</u>
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Data scadenza Expiry Date	<u>20.10.2026</u>	Data revisione Revision date	<u>18.10.2023</u>
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Paolo Taddia

Venice & Verona Management  
System Certification, Head

**RINA Services S.p.A.**  
Via Corsica 12 - 16128 Genova Italy



SGQ N° 002 A

Membro degli Accordi di Mutuo  
Riconoscimento EA, IAF e ILAC  
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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



Building  
trust  
together.

# Certificate

CISQ / RINA has issued an IQNET recognized certificate that the organization:

## **LEDRAGOMMA S.R.L.**

**ZONA INDUSTRIALE VIA GIOVANNI DE SIMON S.N.C. 33010 Osoppo (UD) ITA**

has implemented and maintains a/an

### **Medical Devices - Quality Management System**

for the following scope:

**DESIGN, DEVELOPMENT AND MANUFACTURE OF NON-ACTIVE PLASTIC DEVICES FOR PHYSIOTHERAPY AND REHABILITATION.**

which fulfills the requirements of the following standard:

### **EN ISO 13485:2016**

Issued on: **2023-10-18**

First Issued on: **2008-10-21**

Expires on: **2026-10-20**

All details about any legal entities, operative units and related activities included in this certificate are contained in CISQ/RINA original certificate no.: **DM/08/22**

Registration Number: **IT-110463**

**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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\* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)