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CERTIFICATO N. **ICIM-13485-009524-03**  
CERTIFICATE No. \_\_\_\_\_

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

## ORTHODONTIC MANUFACTURER SIA SRL

SEDE CENTRALE / HEADQUARTER

ZONA INDUSTRIALE SNC 81050 ROCCA D'EVANDRO IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO  
FOR OPERATIVE UNITS SEE ATTACHMENT

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

Progettazione, produzione e immissione sul mercato di dispositivi medici per odontoiatria (ortodonzia, endodonzia, conservativa, implantologia). Lavorazione conto terzi su dispositivi medici dentali.

*Design, production and marketing of medical devices for dentistry (orthodontics, endodontics, conservative dentistry, implantology). Third party processing of dental medical 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  
20/12/2005

EMISSIONE CORRENTE  
CURRENT ISSUE  
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DATA DI SCADENZA  
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03/11/2026

Vincenzo Delacqua  
Rappresentante Direzione / Management Representative

**ICIM S.p.A.**

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



N° 0004MS



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.



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Allegato al CERTIFICATO N.  
*Attachment to CERTIFICATE No.*

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## ORTHODONTIC MANUFACTURER SIA SRL

Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:  
*In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:*

ZONA INDUSTRIALE SNC 81050 ROCCA D'EVANDRO IT - Italia	Progettazione, produzione e immissione sul mercato di dispositivi medici per odontoiatria (ortodonzia, endodonzia, conservativa, implantologia). Lavorazione conto terzi su dispositivi medici dentali.
VIA ARISTIDE LEONORI, 113 00147 ROMA RM IT - Italia	Sede Legale.



N° 0004MS



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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:

**ORTHODONTIC MANUFACTURER SIA SRL**  
**ZONA INDUSTRIALE SNC 81050 ROCCA D'EVANDRO IT - Italia**

**For Operative Units see Annex/Annexes**

has implemented and maintains a/an

**Quality Management System**

for the following scope:

**Design, production and marketing of medical devices for dentistry (orthodontics, endodontics, conservative dentistry, implantology). Third party processing of dental medical devices.**

which fulfils the requirements of the following standard:

**ISO 13485:2016**

Issued on: **2023-11-04**  
First issued on: **2005-12-20**  
Expires on: **2026-11-03**

Registration Number:

**IT-116479 ICIM-13485-009524-03**

  
**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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Annex 1 to IQNET Certificate Number:  
**IT-116479 ICIM-13485-009524-03**

**ORTHODONTIC MANUFACTURER SIA SRL**  
ZONA INDUSTRIALE SNC 81050 ROCCA D'EVANDRO IT - Italia

List of additional locations:

**VIA ARISTIDE LEONORI, 113 00147 ROMA RM IT - Italia**

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This annex is only valid in connection with the original certificate number mentioned above.  
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