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CERTIFICATO N. **0762.2020**  
CERTIFICATE N.

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

**ENKI SRL**

VIA BACHELET 65 - 25062 CONCESIO (BS)  
UNITA' OPERATIVE / OPERATIVE UNITS

VIA BACHELET 65 - 25062 CONCESIO (BS)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

**ISO 13485:2016**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione conto terzi di dispositivi medici monouso,  
microtubi e microcomponenti per uso medicale e non medicale  
*Design and production for third parties of disposable medical devices,  
microtubes and microcomponents for medical use and not medical use*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione  
*Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization*

IL PRESENTE CERTIFICATO E' 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 CERTIFICATION OF MANAGEMENT SYSTEMS*

<b>DATE:</b>	<b>PRIMA CERTIFICAZIONE</b>	<b>EMISSIONE CORRENTE</b>	<b>SCADENZA</b>
	<i>FIRST CERTIFICATION</i>	<i>CURRENT ISSUE</i>	<i>EXPIRY</i>
	2005-12-09	2020-11-17	2023-12-08

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo  
*First certification date is related to issue date of another Certification Body*



*IQNet, the association of the world's first class  
certification bodies, is the largest provider of management  
System Certification in the world.  
IQNet is composed of more than 30 bodies and counts  
over 150 subsidiaries all over the globe.*



SGQ N° 005 A

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

La validità del certificato è subordinata a sorveglianza annuale e riesame completo  
del Sistema di Gestione con periodicità triennale  
*The validity of the certificate is submitted to annual audit and a reassessment  
of the entire Management System within three years*



Organismo di Certificazione Federato CISQ  
**www.imq.it**



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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CERTIFICATO N. 0761.2020  
CERTIFICATE N.

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

**ENKI SRL**

VIA BACHELET 65 - 25062 CONCESIO (BS)  
UNITA' OPERATIVE / OPERATIVE UNITS

VIA BACHELET 65 - 25062 CONCESIO (BS)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

**ISO 9001:2015**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione conto terzi di dispositivi medici monouso,  
microtubi e microcomponenti per uso medicale e non medicale  
*Design and production for third parties of disposable medical devices,  
microtubes and microcomponents for medical and non-medical use*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione  
*Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization*

IL PRESENTE CERTIFICATO E' 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 CERTIFICATION OF MANAGEMENT SYSTEMS*

<b>DATE:</b>	<b>PRIMA CERTIFICAZIONE</b>	<b>EMISSIONE CORRENTE</b>	<b>SCADENZA</b>
	<i>FIRST CERTIFICATION</i>	<i>CURRENT ISSUE</i>	<i>EXPIRY</i>
	2005-12-09	2020-11-17	2023-12-08

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
Management Systems Division - Flavio Ornago

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SGQ N° 005 A

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

IAF: 14

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*CISQ/IMQ has issued an IQNet recognized certificate that the organization:*

## **ENKI SRL**

VIA BACHELET 65 - 25062 CONCESIO (BS)

*has implemented and maintains a*

*Quality Management System*

*for the following scope:*

***Design and production for third parties of disposable medical devices,  
microtubes and microcomponents for medical and non-medical use***

*Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization*

*which fulfills the requirements of the following standard:*

## **ISO 9001:2015**

*Issued on: 2020 - 11 - 17*

*Expires on: 2023 - 12 - 08*

*This attestation is directly linked to the IQNet Partner's original certificate  
and shall not be used as a stand-alone document*

*Registration Number: IT - 130907*



*Alex Stoichitoiu  
President of IQNET*



*Ing. Mario Romersi  
President of CISQ*

### **IQNet Partners\*:**

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 Inspecta Sertifointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia