

CERTIFICATO n°
CERTIFICATE n° **7841**

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

ELKEM SILICONI ITALIA SRL

IT - 21042 CARONNO PERTUSELLA (VA) - VIA ARCHIMEDE 602

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 21042 CARONNO PERTUSELLA (VA) - VIA ARCHIMEDE 602

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' 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

Sviluppo e produzione conto terzi di dispositivi medici a base siliconica.

Contract development and manufacturing of silicone based medical devices.

For information concerning the validity
of the certificate, you can visit the site
www.certiquality.it

The validity of this certificate depends
on annual audit and on a complete
review every three years of the
Management System.

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	21/07/2004
DATA DELIBERA DECISION DATE	10/06/2021
DATA SCADENZA EXPIRY DATE	09/06/2024
EMISSIONE CORRENTE CURRENT ISSUE	16/11/2023



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



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.

Certificate

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

ELKEM SILICONI ITALIA SRL

IT-21042 CARONNO PERTUSELLA (VA) - VIA ARCHIMEDE 602

has implemented and maintains a/an
Quality Management System

for the following scope:

Contract development and manufacturing of silicone based medical devices.

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

ISO 13485:2016

Issued on: 16/11/2023
First issued on: 21/07/2004
Expires on: 09/06/2024

Registration Number: **IT- 37880 - 7841**


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*:

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Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
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LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
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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