

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 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Sviluppo e produzione conto terzi di dispositivi medici a base silconica.
Contract development and manufacturing of silicone based medical devices.

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 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 ISSUE DATE	10/06/2021


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



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

ELKEM SILICONI ITALIA SRL

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

for the following scope

Contract development and manufacturing of silicone based medical devices.

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2016

Issued on: **2021-06-10**

First issued on: **2004-07-21**

Expires on: **2024-06-09**

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-37880**



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