

ALFA OMEGA - S.R.L.

IT - 20900 MONZA (MB) - CORSO MILANO, 26/A

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 44034 COPPARO (FE) - VIA LEONARDO DA VINCI, 57/A

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

Progettazione, produzione e vendita di dispositivi medici a base di sostanze nelle forme di:
soluzioni per aerosol terapia e creme.


Progettazione e produzione di dispositivi medici a base di sostanze per conto di terzi nelle forme di:
liquidi, supposte e cementi.

*Design, manufacturing and sale of substance-based medical devices in the form of: solutions for
aerosol-therapy and creams.*

*Design and manufacturing of substance-based medical devices on behalf of third parties, in the form
of: liquids, suppositories and cements.*

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 **19/11/2020**
FIRST ISSUE
DATA DELIBERA **19/11/2020**
DECISION DATE
DATA SCADENZA **18/11/2023**
EXPIRY DATE
EMISSIONE CORRENTE **19/11/2020**
ISSUE DATE


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:

ALFA OMEGA - S.R.L.

IT - 20900 MONZA (MB) - CORSO MILANO, 26/A

for the following scope

Design, manufacturing and sale of substance-based medical devices in the form of: solutions for aerosol-therapy and creams.

Design and manufacturing of substance-based medical devices on behalf of third parties, in the form of: liquids, suppositories and cements.

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2016

Issued on: **2020-11-19**

First issued on: **2020-11-19**

Expires on: **2023-11-18**

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-119626**



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