

## FIN-CERAMICA FAENZA SPA

IT - 48018 FAENZA (RA) - VIA GRANAROLO 177/3

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 48018 FAENZA (RA) - VIA RAVEGNANA 186

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 impiantabili non attivi riassorbibili e non, in materiali ceramici o materiali compositi e relativi accessori.

Progettazione tecnica di dispositivi medici su misura, paziente specifico, per cranioplastica in idrossiapatite porosa, loro produzione e vendita.

Messa a disposizione sul mercato ed assistenza all'uso di dispositivi medici per il settore della protesica e dell'implantologia.


*Design, manufacturing and sale of non-active implantable medical devices resorbable or not, into ceramic or composite materials and related accessories.*

*Technical design of custom-made medical devices, patient specific, for cranioplasty in porous hydroxyapatite, their production and sale.*

*Making available on the market and assistance of medical devices for joint prosthesis and implant sector.*

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 08/11/2006  
DATA DELIBERA  
DECISION DATE 27/05/2021  
DATA SCADENZA  
EXPIRY DATE 29/05/2024  
EMISSIONE CORRENTE  
ISSUE DATE 27/05/2021

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

**FIN-CERAMICA FAENZA SPA**

IT – 48018 FAENZA (RA) - VIA GRANAROLO 177/3

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IT – 48018 FAENZA (RA) - VIA RAVEGNANA 186

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITÀ CHE È 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 ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione e vendita di dispositivi medici impiantabili non attivi riassorbibili e non, in materiali contenenti sostanze di origine animale e relativi accessori.

Design, manufacturing and sale of non-active implantable medical devices resorbable or not, in material containing substance of animal origin and related accessories.

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

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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:

## FIN-CERAMICA FAENZA SPA

IT - 48018 FAENZA (RA) - VIA GRANAROLO 177/3

for the following scope

*See annex*

has implemented and maintains a

**Quality Management System**

which fulfills the requirements of the following standard

**ISO 13485:2016**

Issued on: **2021-05-27**

First issued on: **2006-11-08**

Expires on: **2024-05-29**

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-48054**



*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 Sertifiointi 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



THE INTERNATIONAL CERTIFICATION NETWORK

Annex 1 to IQNet Certificate Number IT-48054

## **FIN-CERAMICA FAENZA SPA**

### Field of scope

Design, manufacturing and sale of non-active implantable medical devices resorbable or not, into ceramic or composite materials and related accessories.

Design, production and sale of non-active resorbable and non-resorbable implantable medical devices, in materials containing substances of animal origin and related accessories.

Technical design of custom-made medical devices, patient specific, for cranioplasty in porous hydroxyapatite, their production and sale.

Making available on the market and assistance of medical devices for joint prosthesis and implant sector.

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