

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: C593822 Initial certification date: 08 November 2006 (by different Certification body) Valid: 27 May 2021 – 29 May 2024

This is to certify that the management system of

Fin-Ceramica Faenza S.p.A. - Operative Site

Via Ravegnana, 186 - 48018 Faenza (RA) - Italy

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

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.

Place and date: Høvik, 21 May 2023





For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Ceulie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



Certificate no.: C593822 Place and date: Høvik, 21 May 2023

Appendix to Certificate

Fin-Ceramica Faenza S.p.A. - Operative Site

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Fin-Ceramica Faenza S.p.A Operative Site	Via Ravegnana, 186 - 48018 Faenza (RA) - Italy	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.
Fin-ceramica Faenza S.p.A Registederd Address	Via Granarolo, 177/3 - 48018 Faenza (RA) - Italy	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.