

MANAGEMENT DECLARATION AND QUALITY POLICY

This manual describes the policy, criteria and procedures adopted in order to define the objectives, the management methods, the responsibilities and the authority guidelines to implement and apply the Quality Management System of FIN-CERAMICA FAENZA.

The Corporate Quality System is *organised* in compliance to the following requirements:

- ISO 9001: 2015
- EN ISO 13485: 2016 as amended by A11:2021
- Directive 93/42/EEC as amended by directive 2007/47/EC
- Regulation (EU) 2017/745 pertaining to medical devices
- Volume 4 good manufacturing practice, part I, current edition (GMP)
- Code of Federal Regulation title 21, part 820, current edition (21CFR820)
- Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulation 2002
- Medical Device Regulation UK MDR 2002

The implementation of the Quality Management System is ensured through the adoption of a quality plan, applied to the corporate organization and its processes. The quality management system complies with sector-related applicable standards, both for standard products and for custom-made medical devices.

The quality of the products and of the services provided by FIN-CERAMICA FAENZA is a major and vital factor for the company's competitiveness and, as a consequence, also for the wealth of anyone working within the Company.

With this declaration, the Management aims at documenting its leadership and ensuring its commitment to satisfying all applicable mandatory requirements of the quality management system and preserving its efficiency, so as to guarantee and preserve the safety and functionality of the devices manufactured and sold by the Company.

Moreover, the Management shall:

- Maintain an appropriate quality policy for the purposes and context in which FIN-CERAMICA FAENZA operates, in order to be able to support its own strategic purposes;
- Communicate the importance of effective quality management, in compliance with the requirements of the Quality Management System;
- Promote improvement, by driving and supporting staff participation, so that they may contribute to the Quality Management System efficacy.

The quality-oriented policy may not and shall not concern only a limited number of people or functions, it shall instead involve all personnel since each person's performances affects the final result of the product offered to our Customers.

Each Function Manager identified herein is supported by the Management and is directly responsible for the implementation of the Quality Management System requirements within the scope of the field of competence.

The Quality Assurance Manager is responsible for the content, updating and distribution of this manual; as Management Representative, he/she is supported by the Management in order to ensure that the Quality Management System obtains the expected results also in the event of difficulties related to quality that QA is unable to solve autonomously or through the organization.

We fully agree with and approve the declarations concerning FIN-CERAMICA FAENZA's Quality Management System.

This declaration shall be reviewed during the Management review at least once a year, and if necessary shall be revised or otherwise confirmed to ensure its continuous applicability.

Chief Executive Officer
Gianluca Fantini

Date 08/03/22

