

MANAGEMENT DECLARATION AND QUALITY POLICY

The Quality Manual of FIN-CERAMICA FAENZA describes the policy, criteria and procedures adopted in order to define the objectives, the management methods, the responsibilities and the authorities to implement and apply the Quality Management System to the organization.

The Corporate Quality System complies with the relevant requirements of:

- ISO 9001: 2015
- ISO 13485: 2016
- Directive 93/42/EEC amended by Directive 2007/47/EC
- Volume 4 good manufacturing practice, part I, current version (GMP)
- Code of Federal Regulation Title 21, part 820 current version (21CFR820)
- Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulation 2002
- Korean Good Manufacturing Practice.

The implementation of the Quality Management System is guaranteed by the adoption of a quality plan, applied to 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 the services provided by FIN-CERAMICA FAENZA is a factor of the greatest importance for the company's competitiveness and, as a consequence, also for the wealth of anyone working within the Company.

With this declaration, the Management intends to demonstrate leadership and ensures its commitment to meet any applicable regulations, satisfying all the requirements of the Quality Management System and maintaining its efficiency, so as to guarantee and preserve the safety and functionality of the devices manufactured and sold by the Company.

Moreover, the Management will:

- Maintain an appropriate quality policy for the purposes and context in which FIN-CERAMICA FAENZA is working, in order for it to be able to provide support for 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, in order to contribute to the efficacy of the Quality Management System.

The pursuit of quality may not and shall not concern only a limited number of people or functions, on the contrary it shall involve all personnel since the performance of each person influences the final result of the product offered to our Clients.

Each Function Manager identified within the Quality Manual has the support of the Management and is directly responsible for the implementation of the requirements of the Quality Management System for the same area or service.

The Quality Assurance Manager is responsible for the contents, the updating and the distribution of the Quality Manual. As Management Representative, the Quality Assurance Manager has the support of 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 organizational structures.

We fully agree with and approve that stated with regard to the FIN-CERAMICA FAENZA Quality Management System.

This declaration shall be reviewed during Management review at least once per year, if necessary revised or otherwise confirmed to ensure its current adequacy.

Chief Executive Officer
Gianluca Fantini

Date

06/03/2018