

QUALITY POLICY

Management is constantly committed to communicating to all personnel its determination to operate within a Quality Management System compliant with the UNI CEI EN ISO 13485:2016 standard, as confirmation of the company's cultural values, which can be identified as follows:

- ✓ *Protecting the health of Customers and Patients who are the end users of the products;*

Quality (understood also as assurance of product safety) is an essential requirement to offer patients and their families the fullest confidence that the medical devices we manufacture meet the requirements for which they were designed, ensuring a high level of safety. Therefore, for us, Quality translates into Quality for the patient.

- ✓ *Constant focus on maintaining the effectiveness of processes and the organisation;*

Always ensuring consistent effectiveness of the company management system, procurement processes, production, product configuration control, and distribution of medical devices, etc., through a dynamic Quality Management System that is continuously focused on identifying the organisation's weak points and updating itself in response to new Laws, Standards and internal organisational changes—also through careful and prudent management of costs and expenses.

In line with these guiding values, Management believes that the following are fundamental factors for developing and strengthening the company's competitiveness in the market:

- ✓ *compliance, for our medical devices, with regulatory obligations as well as those provided for by the MDR Regulation 745/2017;*
- ✓ *having a Quality Management System that, thanks to the collaboration of all personnel, can prevent, detect and correct non-compliances;*
- ✓ *compliance with all legal and regulatory requirements concerning sterile and non-sterile medical devices and our quality system;*
- ✓ *an adequate and dynamic training plan capable of ensuring a high level of competence and maintaining an ongoing awareness of quality-related issues.*

The General Manager defines the numerical improvement objectives to be achieved, encouraging individual Managers to identify such objectives within the activities under their responsibility. The objectives are defined and the progress toward achieving them is verified during specific meetings.

A special commitment is dedicated to stimulating the participation of all personnel in achieving the objectives indicated above, through a program of continuous education and training on Quality-related topics and on technical and managerial aspects.

Such participation will be pursued through general training and awareness initiatives for personnel and by adopting specific training on the most critical aspects of work activities.

Management firmly believes that only through collaboration at all levels will the company be able to reap the greatest benefits from the programs defined above.

Rev. 08 - 02/03/2026

San Pietro Viminario, 02/03/2026

Management:

