



Quality Policy

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The company has always been attentive to the principles of Quality which it has pursued over the years through the work of all its collaborators. The maintenance of its Quality Management System continued in accordance with the UNI EN ISO 9001 standard as it constitutes a strategic factor of competitiveness and qualification on the market, as well as evidence of the efforts made in pursuing the continuous satisfaction of all its customers and interested parties. The maintenance of its Quality Management System also continued in accordance with the UNI CEI EN ISO 13485 standard.

The Quality Management System is based on an approach based on the assessment of risks and opportunities, which allows the organization to determine the factors that could generate process deviations with respect to the ISO 9001 and ISO 13485 standards and to implement preventive controls to minimize negative effects and best seize the opportunities offered by the market by anticipating trends.

The Quality Policy is defined by ensuring that:

1. It is appropriate for the purposes of the Organization assessed and defined during the Management Review
2. Complies with the requirements of the QMS and its maintenance
3. Provides for a system for defining and reviewing objectives during the Management Review, ensuring their continued suitability
4. It is communicated and understood within the Organization

In particular, in the person of its General Manager and the Board of Directors, the company pursues the following objectives:

1. Always maintain a high level of satisfaction among interested parties, in particular its customers, through a commitment to compliance with the indicated standards and regulatory requirements;
2. Facilitate the participatory and sharing process among its people, in particular employees and collaborators;
3. Always ensure high and adequate technical skills to be applied in the research and development, design and production sectors;
4. Carry out each assessment on the basis of objective evidence and in compliance with the rules and regulations in use;
5. Ensure that company processes are carried out according to the best quality standards, in full compliance with the required technical requirements, the contracts agreed with the customer and the mandatory legislation;
6. Develop the culture of continuous improvement within the company and the ability to work towards objectives;



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7. Guarantee that the company activity achieves the set objectives, particularly in terms of turnover and margins.
8. Ensure that staff are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives

The organization is committed to ensuring continuous monitoring of the performance and safety of devices placed on the market through a structured post-market surveillance process aimed at the systematic collection, analysis, and evaluation of information derived from the real-world use of the devices. This information is used to confirm continued compliance with applicable requirements, identify any needs for improvement, update risk assessments, and—where necessary—promptly initiate corrective, preventive, or vigilance actions.

Administrators and collaborators must be committed every day to pursuing the defined company objectives.

The Board of Directors and the General Management undertake to ensure that this Policy is understood, shared and implemented by all its employees and collaborators and at the same time undertake to share it with all interested parties, to adopt and identify the necessary resources to meet the set objectives and to monitor the quality management system by carrying out the required reviews, with a view to continuous improvement.

The Management Representative, who has the authority and responsibility to ensure that the system processes are documented, to report to top management on the progress of the activity and to promote and disseminate the principles of the system within the organization, is Mr.Andrea Maffezzoni.

This Quality Policy is updated based on the indications of the Management Review.

The General management _____