
 <b>QUALITY MANAGEMENT</b>	<b>QUALITY POLICY</b> <i>Gruppo Bioimpianti Srl</i>	<b>AQ0000</b>
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The main target of Gruppo Bioimpianti Srl is to establish itself in the context of the medical sector as one of the main manufacturers of implantable Medical Devices for Orthopaedics and Traumatology, ensuring that its name is associated to the image of a company manufacturing innovative and high-quality products, through the constant drive for continuous improvement and the pursuit of the maximum satisfaction of the patient, in compliance with applicable standards.

In order to achieve this purpose, it is of fundamental importance that the concept of quality is pursued in all areas and parts that represent the context in which the company operates, and in particular:

1. **Design.** Design is a key element for Gruppo Bioimpianti Srl as it allows it to keep abreast of the state of the art and any technological innovations offered by the market and therefore to offer modern, reliable, effective and appealing devices to the market and to its customers, thus enabling these concepts to be associated with the image of Gruppo Bioimpianti Srl itself. It is of fundamental importance that the design follows a structured approach and involves several resources, with different skills and as defined by dedicated internal procedures, and that during this phase any regulatory requirement and the needs of the customer are considered, both for implantable devices and for instruments.
2. **Outsourcing.** Considering how most of the manufacturing process of the devices of Gruppo Bioimpianti Srl is outsourced, both for those activities that are then subject to incoming verification by Quality Control such as mechanical machining or surface treatments and for those activities that are subject to validation such as sterilisation, it is essential to rely on qualified suppliers sharing the same attention towards the concept of Quality, regardless of their size, structure or peculiarities.
3. **Organization.** Fundamental to achieving the set target is that the concept of Quality is shared at all company levels. Each employee is in fact responsible for the Quality of their own work, which inevitably turns out to be a determining element for the final Quality that is perceived by the customers, both with regard to the product and the support offered them, in the performance of the various activities. It is essential that all personnel are aware of their importance and of the relevance of the tasks they perform, that they share the same company mission and that they feel as an active part in the path to achieving the set objective. This is why the Quality Policy, the Quality Manual and the objectives that are defined by the company leadership, including those for Quality improvement, are shared at all company levels. In order for all employees to be aware of their role as Quality Responsible for the work they are in charge of, it is considered necessary to carry out appropriate training, updating and empowerment of personnel.
4. **Customer support.** In order to pursue the objective of maximum customer satisfaction, it is essential to offer a high-quality, tailor-made customer support service, with the aim of giving value to the customer by making him feel like an active part of the process itself and trying wherever possible to meet his needs, offering maximum availability and carrying out activities such as, for example, direct training courses, support in the operating room, etc.
5. **Planning.** In order to be able to pursue the policy of continuous improvement over time and thus achieve the company's set goal of customer satisfaction, it becomes necessary to plan activities and

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especially objectives for quality improvement and to evaluate them. This activity is carried out annually during the Management Review.

Each employee of Gruppo Bioimpianti Srl is responsible for carrying out their own duties and is asked to adopt a proactive attitude by always performing their work with a critical sense in a risk based approach, assessing all the possible risks that may be associated with the activities carried out and at the same time reflecting on the possible opportunities for the Company that may arise from these (Risk Based Thinking). This approach is obviously also adopted by the QMR for all aspects pertaining to the Quality Management System and by Top Management in the assessments and decisions made during their operations.

Considering the type of products offered by Gruppo Bioimpianti Srl, it is essential that the company meets the appropriate mandatory obligations that require the maintenance of Quality System and product certifications: the basic reference is represented by the European Regulations in force in the field of medical devices, i.e. EU Regulation 2017/745 and European Directive 93/42/EEC, implemented by Decree Law 46/97 and updated by European Directive 2005/50 (Legislative Decree of 26.04.2007) and Directive 47/2007/EEC. A further significant element demonstrating the efficiency and importance attributed to its Quality Management System is the obtaining and maintenance of certifications demonstrating its compliance with the main regulations in terms of Quality, namely ISO 9001 and ISO 13485, current editions.

In parallel with the above, in order to be able to offer high-quality products and aim at achieving a complete level of customer satisfaction, Gruppo Bioimpianti Srl has for several years been using a Code of Ethics established to express the commitments and ethical responsibilities in the conduct of business and professional activities of the company and its collaborators at any level. This includes the set of principles and guidelines which observance is of crucial importance for the achievement of company and business objectives, for the smooth running of activities, for the reliability of management and for the company's image.

Fabio Bedini  
 CEO Gruppo Bioimpianti S.r.l

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