

Section 1	DECLARATION by the management regarding quality policy and objectives

Our main objective is to offer high-quality products which would satisfy our customers' requirements to a maximum degree.

The Company management assumes responsibility for establishing, maintenance and continual improvement of a Quality management system, and declares the following basic principles underlying its policy:

- Orientation to customers and other interested parties we recognize our responsibility and make every effort to satisfy current and future needs of all our customers to the highest degree, meeting all statutory and normative requirements in effect;
- Management leadership we accept our responsibility for the maintenance of functioning systems. We create favourable conditions which stimulate the company employees for valuable participation in the quality management processes, as well as to show initiative in performance of the activities related thereto.
- **Commitment of people** we believe that people are the most valuable resource of the company. We endeavour to create an atmosphere in which people would feel motivated, satisfied and totally devoted to achievement of the company objectives.
- Fact-based approach to decision-making: the decisions at all levels of the company are based on updated and trustworthy information. The implementation of a functioning system for communication and management of the documented information create conditions for adoption of the right decisions.
- **Process approach:** the products manufactured by the company are a result from ongoing interrelated basic and auxiliary processes which are understood and managed not separately but as a coherent system.
- Mutually beneficial relations with providers and interested parties: based on the
 principle that first-class materials, services and equipment are needed for the manufacture
 of high-quality products, the company selects its partners from among providers offering
 high-quality supplies.
- Improvements aimed at a higher level of quality: through continuous monitoring and analysis of the processes at the company and undertaking effective corrective actions, the management aims at continuing improvement of the quality.

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For achievement of its main objective – manufacture and sale of high-quality products which satisfy our customers' requirements to a maximum degree – the company management has set itself the following goals:

- 1. Production of products corresponding to the requirements of current European standards for electromedical devices and quality management of the production process
- 2. Availability and maintenance of appropriate equipment, adequate work instructions and trained personnel for its use.
- 3. Increasing the competence and motivation of human resources in the company.
- 4. Continuous monitoring of the market and seeking feedback from customers and distributors.

The company management warrants that:

- the organization has at its disposal the resources required for establishment, maintenance and further development of a quality management system;
- it takes special care so that the implemented system would function efficiently and in compliance with the requirements of the ISO 13485:2016, ISO 9001:2015 standards and MDR 2017/745 EU Regulation on medical devices.

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