

Declaration of Commitment

Kufstein, April 4th, 2006

It is our premise to comply with all national and European standards. Laboratories at our production plants as well as independent testing institutions like the Austrian Institute for Medical Products (Österreichisches Institut für Medizinprodukte) in Vienna are responsible for regular product testing, which guarantees our clients constant high product quality.

Due to the obligation of every company to exercise diligence in terms of quality management of its products and services, we define our quality policy by means of the present quality management system.

The Meditrade Online QM System is a description of the quality management system we have defined. The application of this system guarantees that all the organizational, commercial and technical activities that influence quality are planned, controlled and monitored and that the contractual requirements are fulfilled.

Our QM system is based on the requirements of the ISO standards 9001:2000, ISO 13485:2003, on the Austrian Medical Products Act (Medizinproduktegesetz) and on the dispositions of bodies of rules and regulations as well as on the instructions to be followed according to the contract.

Clause 7.3 Design and Development shall not be applied. The product development will be carried out in the manufacturer's works. We distribute market-ready products that have already been authorized.

Clause 7.5.4 Customer Property shall not be applied. Only new products will be delivered to the clients, there shall be no reprocessing treatment.

Clause 7.6 Control of Monitoring and Measuring Devices shall only apply in a limited way, because product testing is outsourced to external service providers. Only monitoring, no measuring devices are used.

According to the ISO standard 14971 the benefits of our products must exceed their risks. A possible residual risk must be defensible.

According to this declaration all the employees of the company are obliged to do their jobs according to the rules of the QM system and to its process or working instructions in order to make sure that the quality of the products and services of our company fulfills our customers' requirements and that it is constantly enhanced.

The quality manager shall be responsible for the planning, monitoring and correction of the QM system. He is entitled to point out quality problems and is provided with organizational freedom to identify them, to suggest measures and monitor their implementation.

The responsible person of the company evaluates the quality management system by evaluating the results of internal system audits and of the periodic quality reporting.