

# Quality Policy

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# 1. Policy

O3 Enterprise is a company that produces software medical devices in the imaging field and therefore its policy encompasses all the activities, from design to installation and assistance, to produce secure and efficient medical devices. Key objectives, covered by the quality policy and important to prioritize patient safety and customer satisfaction, are:

- **Compliance:** compliance to customers and applicable requirements, thereby fostering trust and satisfaction among the customers;
- **Product safety:** prioritizing device's safety to prevent any harm or adverse events for users;
- **Product effectiveness and accuracy:** providing the most reliable diagnostic information to support doctors in medical reporting;
- **Continuous improvement:** promoting the maintenance and continuous improvements of the QMS and the products themselves. This includes regular reviews, updates, and enhancements to keep pace with technological advancements;
- **Activity control:** overseeing all processes and activities in device development and maintenance to promote customers' satisfaction and product improvement;
- **Data security and privacy:** ensuring confidentiality, integrity and availability of sensitive data;
- **Risk management:** implementing a comprehensive risk management process to identify, assess, and mitigate potential risks associated with the development, deployment, and use of the medical devices;
- **Documentation and traceability:** maintaining documentation throughout the development lifecycle of the medical devices;

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- **Communication and transparency:** promoting comprehension of the quality policy within the organization, through continuous training and communication with employees.

To maintain the effectiveness of the QMS that prioritizes patient safety, regulatory compliance and customer satisfaction, QMS of O3 Enterprise meets:

- Regulatory requirements: EN ISO 13485:2016, MDR 745/2017, Directive 93/42/EEC;
- Customer requirements: Top Management, Product Manager and Project Manager interface with customers to provide a product as close as possible to their requirements. Customers can communicate directly with the Assistance Team by phone, email and Jira ZSD project;
- Requirements related to product changes and organizational goals.

Compliance to all these requirements and their updates allows to ensure the ongoing effectiveness of the QMS.

## 2. Management Commitment

Top management commitment to the development and implementation of the QMS and maintenance of its effectiveness is demonstrated by:

- a) communicating to the organization the importance of meeting customers as well as applicable regulatory requirements. In fact the majority of improvements derives from the customer feedback and requirements;
- b) establishing the quality policy;
- c) ensuring that quality objectives are established;
- d) conducting management reviews;
- e) ensuring the availability of resources.