ISO 13485:2016 Standard

Medical Devices – Quality Management System – Requirements for Regulatory Purposes

WHAT IS THE ISO 13485:2016 STANDARD?

The **Quality Management System** according to the **ISO 13485 Standard** is a documented set of interrelated processes and forms that establishes, implements, and maintains the requirements of the Standard, aiming to satisfy customers and regulatory requirements in the field of medical devices. Adopting the system is a strategic decision that guides a company to improve its performance and create a solid foundation for sustainable development.

WHO IT APPLIES TO

The **ISO 13485:2016** Standard specifies the requirements for a **Quality Management System** that can be implemented by any organization, regardless of size or type, that operates in one or more stages of the lifecycle of a medical device. Such stages include:

- Design and development
- Production
- Storage and distribution
- Installation and maintenance
- Technical support and related services
- Decommissioning and disposal of medical devices

The application of the Standard's requirements can extend, either voluntarily or contractually, to suppliers or other external providers of products or services, such as:

- Raw materials, components
- Sterilization services
- Calibration services
- Distribution services
- Maintenance services, etc**.**

BENEFITS

Compliance with Regulatory Requirements: For manufacturers of medical devices, implementing a **Quality Management System** according to the **ISO 13485 Standard**, harmonized with **Regulations 2017/745 (MDR) & 2017/746 (IVDR)**, enhances the compliance evaluation of the manufacturing of medical devices. For importers and distributors, implementing the system serves as an excellent tool for complying with the requirements of the above Regulations for the activities of importing and distributing medical devices.

Additionally, in combination with certification according to the **Ministerial Decision 1348/2004 "Good Distribution Practices for Medical Devices"** – a service also offered by **EUROCERT** – the requirements of national legislation are met, which concern public sector suppliers in the health sector and registration in the **EKAHPY Suppliers Registry**.

Increased Efficiency and Productivity: Implementing a quality management system enhances efficiency and productivity by streamlining processes related to the manufacturing, distribution, installation, and maintenance of medical devices.

Reduced Recall Risk: A significant advantage of implementing a quality management system according to the **ISO 13485 Standard** is the reduced likelihood of medical device recalls, as non-compliant products are not released to the market. This increases the confidence of customers and users of medical devices due to the manufacturer's commitment to providing safe and reliable products.

Added Value: Achieving certification according to the **ISO 13485 Standard** demonstrates to potential customers the company's commitment to maintaining strict requirements in the manufacturing of safe, high-performance medical devices. As a result, sales prospects expand, and customer and user confidence in medical devices increases.

WHY CHOOSE EUROCERT

- **EUROCERT** is the largest Greek independent certification body accredited by ESYD, with activities in over 40 countries worldwide. Certification with Eurocert means evaluation and acceptance by a reliable accredited and recognized certification organization.
- **EUROCERT** has capable and experienced staff and partners, who as inspectors and/or technical experts conduct high value-added inspections and audits for your business.
- **EUROCERT** ensures you are continuously informed about any local or international developments that interest you according to your certification field.
- **EUROCERT** is capable of providing your business with a comprehensive solution for management system certification, having accreditation in a very wide range of certification services.

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