ISO 13485

MEDICAL DEVICES
QUALITY MANAGEMENT
SYSTEMS

SERVICE FINAL USERS

This service is intended for any company:
• manufacturing or placing on the market medical devices, in-vitro diagnostic medical devices
• designing, manufacturing or testing devices or components or sub-assemblies of such devices for the benefit of third parties
• designing, developing or providing services related to medical devices, such as for example sterilization, distribution, installation and maintenance of medical devices, surface finishing or packaging.

CONTEXT

In order to place a medical device on the market according to Regulation (EU) 2017/745, or Regulation (EU) 2017/746, the Manufacturer must develop and implement a comprehensive quality management system or production quality assurance/guarantee system based on the risk class of such product.

The ISO 13485 standard specifies the requirements for a quality management system that can be used by an organization in the design, development, production, installation and maintenance of medical devices, as well as in the design, development and the provision of related services.

SERVICE

Certiquality provides companies operating in the medical devices sector with certification services for quality management systems according to the ISO 13485 standard.

Companies producing Medical Devices can also easily integrate the Quality System compliant with the ISO 13485 standard, with the additional requirements of the ISO 9001 standard, regarding the customer satisfaction and the continuous improvement of organizational performance and processes.

BENEFITS

The benefits resulting from certification according to ISO 13485 are represented by the possibility of:

- demonstrating the ability to **supply medical devices** and **provide related services** that meet customer requirements and comply with the applicable regulatory requirements;
- facilitating any **qualification process** with a manufacturer wishing to outsource, partially or totally, the production activities of a medical device.

CERTIFICATION PROCEDURE

The main stages of the certification process include:

- An optional preliminary audit, which allows to evaluate the status of the company management system in relation to the requirements of the ISO 13485 standard. A gap analysis will identify the system's strengths and potential areas for improvement;
- The certification audit, with the aim of assessing the compliance of the management system with the requirements of the ISO 13485 standard, through a documentary analysis and on-site findings;
- Issuance of the certificate of conformity;
- Annual surveillance audits and triennial renewal audits.

ISO 13485 audits can be carried out jointly with audits according to the ISO 9001 standard and according to the requirements of Regulation (EU) 2017/745.

TRAINING

Certiquality can integrate **classroom training** to its activities, which can also be dispensed on your company's premises. Courses cover various topics such as:

- Regulation (EU) 2017/745;
- Risk Management in the production of Medical Devices according to the ISO 14971 Standard;
- the ISO 13485 Standard (Quality System for Medical Devices);
- Clinical Evaluation of Medical Devices.