



ISO 13485

THE most important standard for quality management for medical device manufacturers!

ISO 13485 – Quality management system accompanied by en.co.tec!

ISO 13485 gives manufacturers a comprehensive framework to consistently meet regulatory and customer expectations, safeguarding that all products and services fulfill applicable statutory requirements for safety and performance.

ISO 13485:2016 is the state-of-the-art standard for medical device manufacturers and, in practice, also a requirement for suppliers of components and assemblies. The main focus is on regulatory compliance, risk management, traceability, and expanded documentation requirements.

Around 25,000 organizations worldwide are certified to ISO 13485. en.co.tec is proud to have contributed significantly to this figure by supporting around 75 quality management system certifications to ISO 13485 in the DACH region alone.

Support from en.co.tec - how do we help you?

Whether a company already has a quality management system (QMS)—for example, according to ISO 9001—or whether a new QMS is to be implemented together, en.co.tec provides highly individualized support in three simple steps to ensure instant compliance with the quality management requirements of EU regulations (MDR / IVDR) and/or ISO 13485.

No inflated documentation - just exactly what is needed!

Support and guidance from en.co.tec are provided in all phases of implementing ISO 13485:

Step 1: Initial assessment and implementation

Professional consultants assist with analyzing, implementing and documenting company processes for the quality management system.

Step 2: Auditing

The created QMS is reviewed by an independent en.co.tec auditor during an internal audit. If a company already has a QMS, the assessment also starts with an internal audit.

Step 3: Certification

en.co.tec manages the contact and coordination with the certification body (for ISO 13485) or notified body (for MDR/IVDR), and supports during stage 1 and final certification audits.

How does it continue after certification?

Once your ISO 13485 system certificate has been issued, we are happy to support you with our:

“3-year all-round ISO 13485 Happiness Package”:

- ✓ Maintenance of the quality management system with annual internal audits and
- ✓ significantly discounted priority access to our consulting and training services.

Special topics related to ISO 13485:

We have specialized expertise when it comes to integrating regulatory approval requirements for medical devices with general quality management system requirements, for example:

- ✓ **Software Development:** ISO 13485, Software life cycle processes (EN 62304), risk management (ISO 14971), while simultaneously preparing the technical documentation for product approval.
- ✓ **Beginners in medical technology** (as suppliers, manufacturers with established quality management systems)

Are you planning to implement ISO 13485?

We are happy to support you!

COSTS & SCHEDULE:

Quality management – Implementation of ISO 13485:

- ✓ Approx. 1 year time requirement
- ✓ With own execution: approx. €30,000 - €40,000 en.co.tec consulting costs
- ✓ Without own execution: several times more.
- ✓ Costs for a notified body: significant differences, therefore at least 2 comparison offers recommended.

START DATE

Please allow approximately 8–12 weeks lead time for the start date!

CONTACT

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