

ISO 13485
MEDICAL DEVICES
MANAGEMENT SYSTEMS
CERTIFICATION

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide Medical Devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

Organizations involved in medical device industry see ISO 13485 as the de facto standard towards regulatory compliance.



ISO 13485 certification (also known as “Registration”), is a third-party audit performed by a certification body such as PECB MS who, upon verification that an organization is in compliance with the requirements of ISO 13485, will issue an ISO 13485 certificate. This certification is then maintained through regularly scheduled annual surveillance audits by the registrar, with re-certification of the Medical Devices Quality Management System performed on a triennial basis.

Benefits of implementing ISO 13485 Management System in your organization:

- Global Recognition
- Improved legal and regulatory or contractual requirements compliance
- ISO 13485 Medical Devices Quality Management System (QMS) is very close to the Food and Drug Administration’s (FDA) QSR standards
- Assistance in monitoring supply chain effectiveness
- Increased profit margins
- Improved product safety
- Increased Efficiency
- Proactive error detection and prevention
- Cost Savings
- More Effective Risk Management
- Increased likelihood of meeting Customer Requirements
- More Effective Risk Management
- Increased likelihood of meeting Customer Requirements

Benefits of ISO 13485 Certification to your customers:

- Quality ensured medical devices
- Safe and effective medical devices
- Lower skepticism and increased confidence for end-customer
- Boost of loyal customers and potential customers
- Increased profit margins

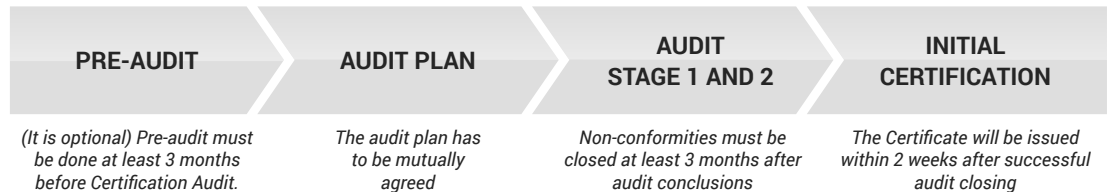
PECB MS is specialized in the certification of management systems on a wide range of international standards. As a global provider of audit and certification services, PECB MS offers its expertise on multiple fields, including but not limited to Medical Devices Management.

We help organizations to show commitment and competence with internationally recognized standards by providing this assurance through certification against rigorous, internationally recognized competence requirements. With a global coverage of over 150 countries worldwide, our mission is to provide our clients comprehensive services that inspire trust, continual improvement, demonstrate recognition, and benefit society as a whole.

To find out how you can obtain the ISO 13485 Certification, contact ms@pecb-ms.com

PECB MS CERTIFICATION PROCESS

YEAR 1 (INITIAL CERTIFICATION)



YEAR 2 (1st SURVEILLANCE AUDIT)



YEAR 3 (2nd SURVEILLANCE AUDIT)



RE-CERTIFICATION AUDIT

Within two months before the triennial certificate expiration

For additional information, please contact us at ms@pecb-ms.com or visit www.pecb-ms.com