ISO 13485
MEDICAL DEVICES MANAGEMENT SYSTEMS CERTIFICATION

iCERTWORKS
TRAINING & 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.

PECB

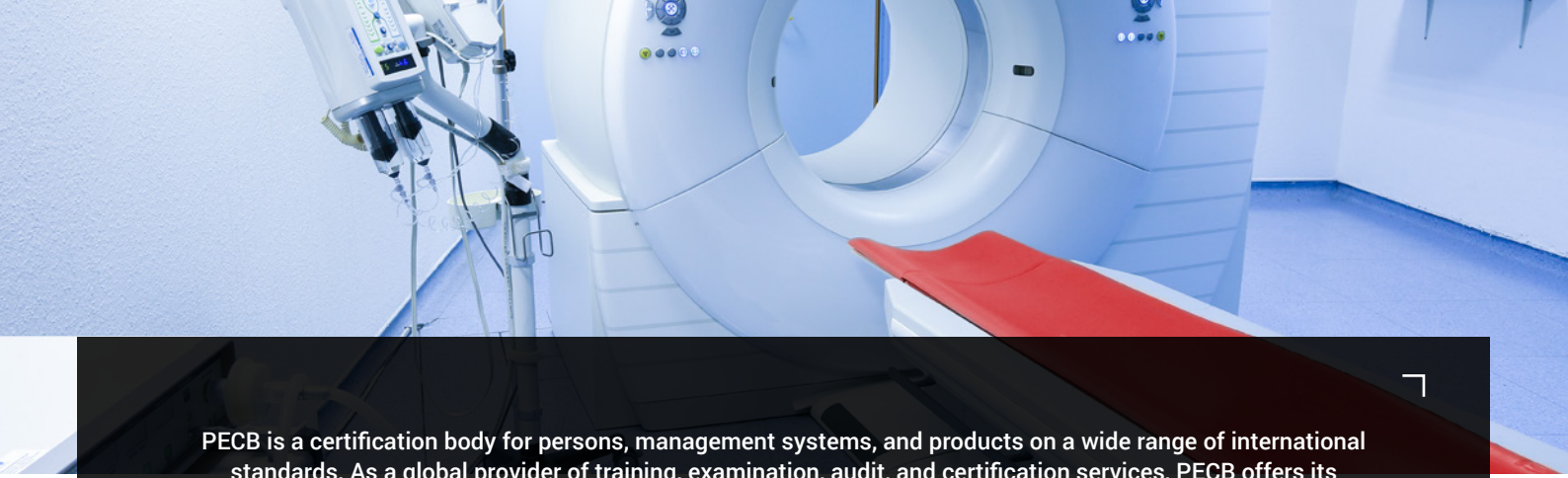
ISO 13485 certification (also known as “Registration”), is a third-party audit performed by a certification body such as PECB who, upon verification that an organization is in compliance with the requirements of ISO 13485, will issue an ISO 13485 certificate. This certification is then maintained through 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
- 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

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



PECB is a certification body for persons, management systems, and products on a wide range of international standards. As a global provider of training, examination, audit, and certification services, PECB 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 the education, evaluation and certification against rigorous, internationally recognized competence requirements. With a global coverage of more than 900 partners in 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 certification@iCertWorks.com

PECB CERTIFICATION PROCESS

YEAR 1 (INITIAL CERTIFICATION)

PRE-AUDIT	AUDIT PLAN	AUDIT STAGE 1 AND 2	INITIAL CERTIFICATION
This is optional, and it must be done at least 3 months before Certification Audit	*Plan for audit has to be mutually agreed*	*Non-conformities must be closed at least 3 months after audit conclusions*	*Certificate will be issued within 2 weeks after successful audit closing*

YEAR 2 (1st SURVEILLANCE AUDIT) — **YEAR 3 (2nd SURVEILLANCE AUDIT)**

AUDIT PLAN	SURVEILLANCE AUDIT 1	AUDIT PLAN	SURVEILLANCE AUDIT 2
	No longer than 12 months from the initial certification audit		*No longer than 12 months from the 1st surveillance audit*

RE-CERTIFICATION AUDIT
Within two months before the triennial certificate expiration