# ISO 13485
## MEDICAL DEVICES MANAGEMENT SYSTEMS CERTIFICATION

INTI.Q SOLUTIONS

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.

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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
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- 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

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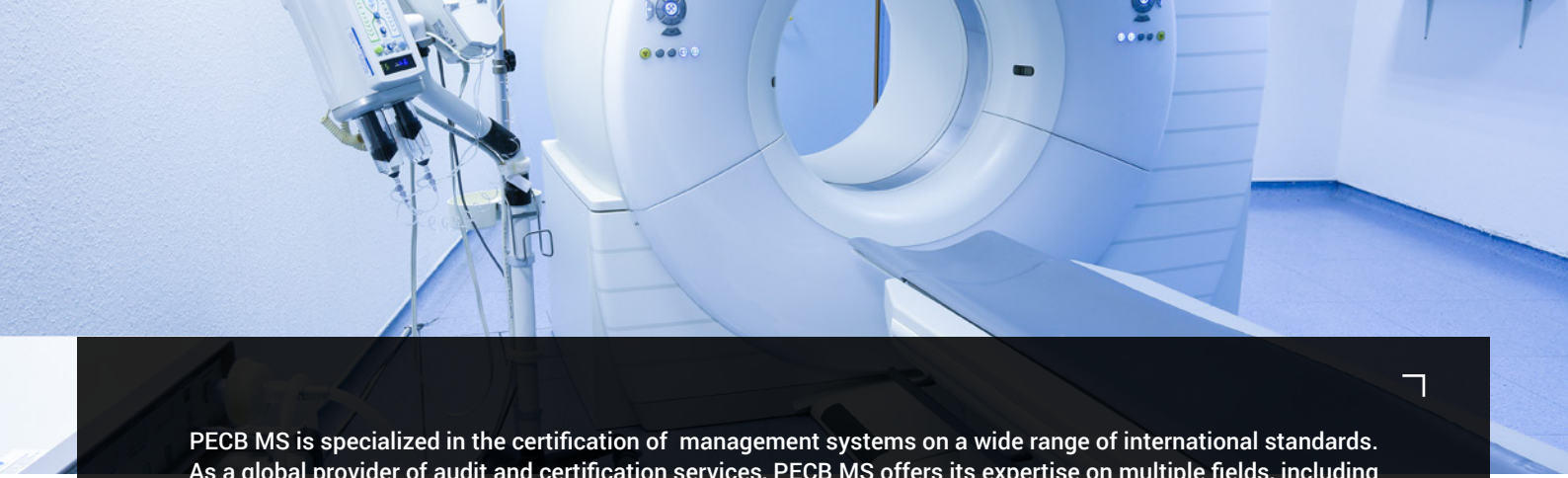

PECB MS is specialized in the certification of management systems on a wide range of international standards. As a global provider of audit and certification services, PECB MS offers its expertise on multiple fields, including but not limited to Medical Devices Management.

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)**

| PRE-AUDIT | AUDIT PLAN | AUDIT STAGE 1 AND 2 | INITIAL CERTIFICATION |
|---|---|---|---|
| *(It is optional) Pre-audit must be done at least 3 months before Certification Audit.* | *The audit plan has to be mutually agreed* | *Non-conformities must be closed at least 3 months after audit conclusions* | *The 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*