Con Cert
Quality Management

When Quality Matters

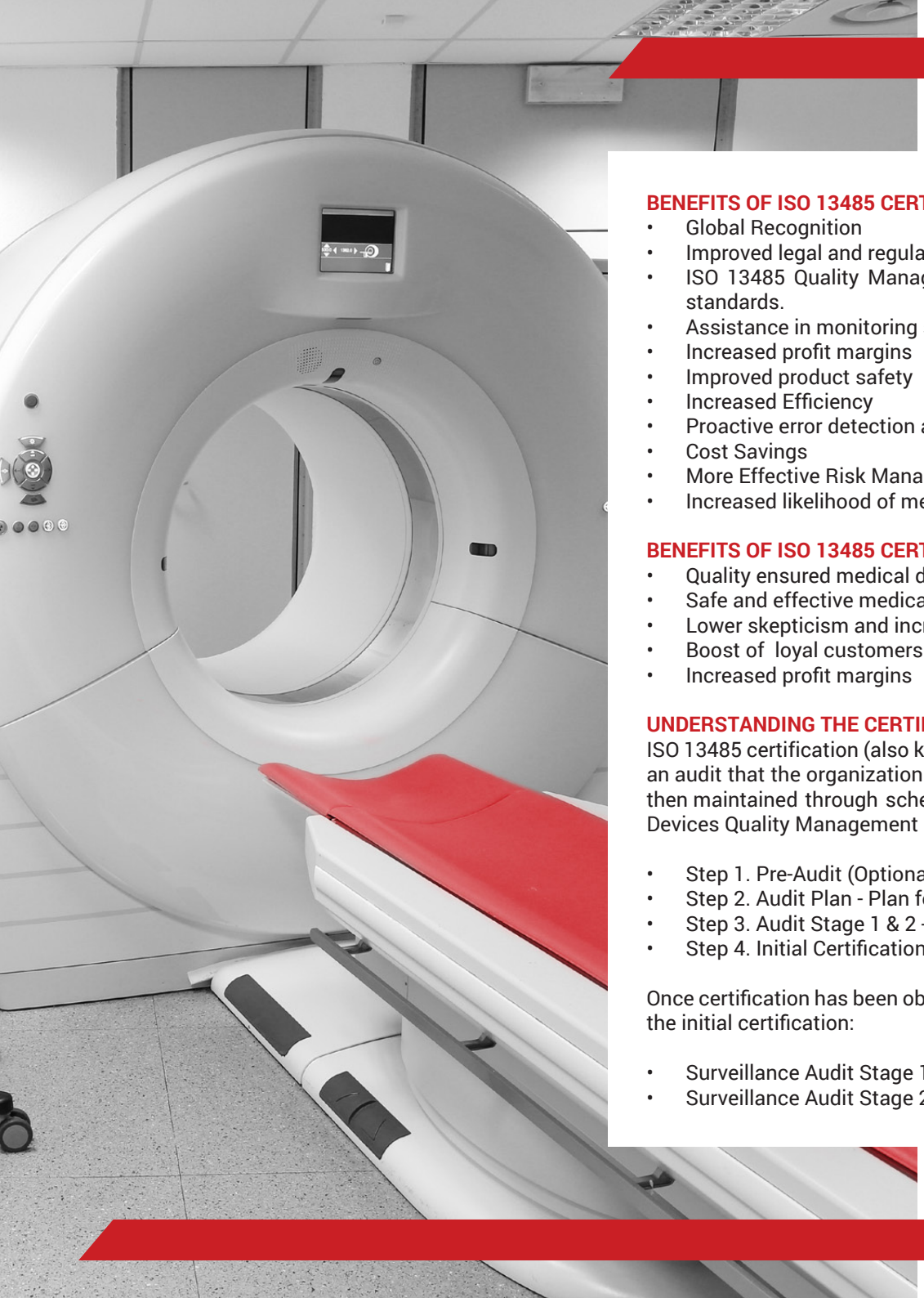
ISO 13485 MEDICAL DEVICES MANAGEMENT SYSTEM CERTIFICATION

MEET CUSTOMER EXPECTATIONS BY CONTINUAL IMPROVEMENT PRACTICES WITH THE ISO 13485 CERTIFICATION

ISO 13485 Medical Devices Management standard 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.

www.ccqm.ch



BENEFITS OF ISO 13485 CERTIFICATION TO YOUR ORGANIZATION:

- Global Recognition
- Improved legal and regulatory or contractual requirements compliance
- ISO 13485 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

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

UNDERSTANDING THE CERTIFICATION PROCESS

ISO 13485 certification (also known as "registration") is granted by a third-party, such as CCQM, upon verifying through an audit that the organization is in compliance with the requirements of the ISO 13485 standard. This certification is then maintained through scheduled annual surveillance audits by the registrar, with re-certification of the Medical Devices Quality Management System performed on a triannual basis.

- Step 1. Pre-Audit (Optional)- It must be done at least 3 months before Certification Audit
- Step 2. Audit Plan - Plan for audit has to be mutually agreed
- Step 3. Audit Stage 1 & 2 - Non-conformities must be closed at least 3 months after audit conclusions
- Step 4. Initial Certification - Certificate will be issued within 2 weeks after successful audit closing

Once certification has been obtained, the organization will be subjected to two surveillance audits within 24 months from the initial certification:

- Surveillance Audit Stage 1 - No longer than 12 months from the initial certification audit
- Surveillance Audit Stage 2 - No longer than 12 months from the 1st surveillance audit

WHY CHOOSE CCQM?

CCQM 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, CCQM offers its expertise on multiple fields, including but not limited to Medical Devices.

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 200 partners in over 120 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, visit www.ccqm.ch/certification

CCQM CERTIFICATION PROCESS

PRE-AUDIT (FACULTATIVE) → STAGE 1 AUDIT → STAGE 2 AUDIT → YEAR 2 (SURVEILLANCE AUDIT) → YEAR 3 (SURVEILLANCE AUDIT)