ISO 13485

MEDICAL DEVICES – QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR REGULATORY PURPOSES

SGS

Why ISO 13485?

ISO 13485 is a globally recognized medical device certification standard to help you demonstrate that your management system can meet product and regulatory requirements.

What is ISO 13485?

ISO 13485 specifies requirements for a quality management system (QMS) to help an organization show its ability to provide medical devices and related services that adhere to user and legal standards.

Organizations can be involved in one or more life-cycle stages, including production, storage and distribution, and installation. It can also be involved in servicing, design and development or associated activities like technical support.

The standard can be used by suppliers or external parties that provide products to organizations.

Key benefits

Certification follows successful completion of an audit and enables you to:

- Produce and distribute devices faster
- Enable systematic process improvement
- Discover ways to improve efficiency and add value
- Gain a competitive advantage
- Monitor supply chains for continuous improvement

Align with the UN Sustainable Development Goals
Implementing ISO 13485 can contribute to:

Homing in on critical areas

From identifying issues to prioritizing ownership and updating processes, ISO 13485 has several key requirements to fulfill.

Key requirement areas

- Outline your organization's strategy and engage stakeholders
- Develop an implementation plan
- Meet any new competency requirements and create awareness for all parties that impact your QMS
- Review and confirm leadership roles, responsibilities and accountabilities
- Determine the systems that manage outsourced products and services
- Review and understand the requirements for risks and opportunities
- Ensure that documented information requirements are understood
- Update the existing QMS to meet the new requirements and verify its effectiveness

Cutting to the core

ISO 13485 contains several core concepts that, if implemented correctly, can help to enhance your organization.

Some core concepts

- The context of your organization
- Interested parties
- Issues, risks and opportunities
- Leaders and risk owners
- Threats and opportunities
- Communications
- Documented information
- Performance evaluation
- Operational planning and control
- Nonconformity and corrections

Implementing ISO 13485

It is essential that ISO 13485 is implemented correctly to reap all of the rewards. We can support you to achieve this through our various training courses.

Key implementation considerations

- Ensure senior management support and commitment
- Engage the entire organization through internal communications
- Compare your existing systems with the new requirements
- Obtain worker, customer and supplier feedback on current systems
- Create an implementation team
- Define roles, responsibilities and schedules
- Start with the basic principles
- Use training and incentives to encourage employee involvement
- Share knowledge on the standard and consider internal auditor training
- Regularly review the system to ensure continual improvement

Why our ISO 13485 services?

With expertise in all major industries, we understand each sector's pain points and have the technical skills and logistical capabilities to ensure realistic outcomes.

What we offer

An audit against ISO 13485 from SGS will help your organization to stand out from the crowd by supporting you to improve performance.

In addition, we offer a range of complementary services:

- In Vitro Diagnostic Regulation (IVDR) Technical Documentation Training Course
- ISO 13485 Medical Devices QMS Auditor/Lead Auditor Training Course
- ISO 14971 Risk Management for Medical Devices Introduction Training Course
- MDR Clinical Evaluation Training Course
- MDR Implementation Training Course
- MDR Internal Auditor Training Course
- MDR Technical Documentation Transition Training Course
- Medical Devices QMS Software Validation Training Course

With a global presence, we have a history of successfully executing large-scale, complex international projects. We speak the language, understand local markets and operate consistently, reliably and effectively globally.

About SGS

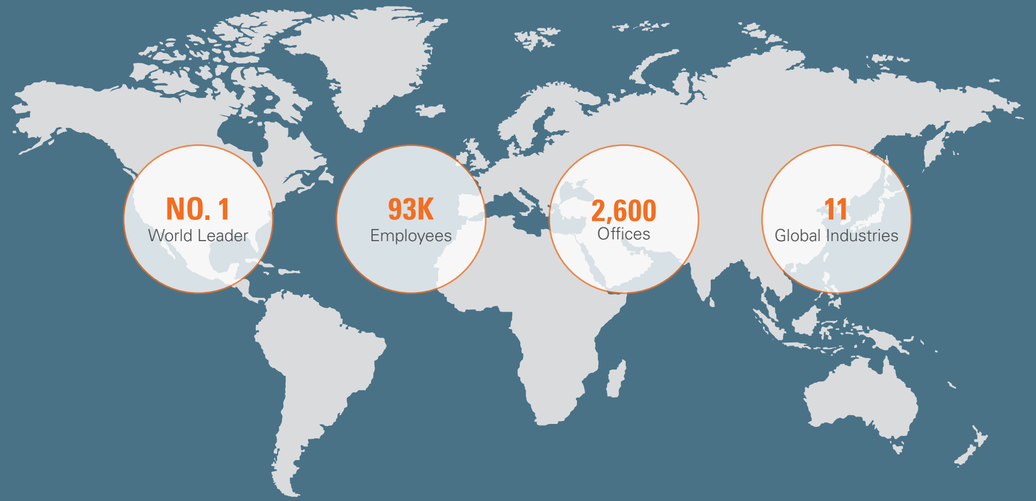
OUR HISTORY

1878
SGS is founded

Mid-20th Century
Diversified into inspection, testing and verification services

1981
Listed on the Swiss Stock Exchange

Today
140+ years in business



About SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 93,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world. Enhancing products, processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your products, services and value chain by increasing performance, managing risks, better meeting stakeholder requirements, and managing sustainability. With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

WWW.SGS.COM

SGS Headquarters
1 Place des Alpes
P.O. Box 2152
1211 Geneva 1
Switzerland

WHEN YOU NEED TO BE SURE