What else we can do for you

Certifications and accreditations on the basis of

- **ISO 9001** Standard applied and recognized world-wide to ensure the quality of processes and results in order to improve the competitive factor. **Relevant for:** Every enterprise. The standard enjoys a high level of recognition in healthcare and related social systems.
- **Regulation MDR (EU) 2017/745** of the European Council: Prerequisite for placing medical devices on the market in the European Union. **Relevant for:** Manufacturers of higher than class I medical devices.
- **ISO 15378** is based on ISO 9001 and additionally comprises all GMP (Good Manufacturing Practices) requirements relevant for primary packaging materials. **Relevant for:** Manufacturers of primary packaging materials for drugs and manufacturers with a special focus on hygiene.
- **MDSAP** The program opens an option for Medical Device Manufacturers to cover the national regulatory requirements of Australia, Brazil, Japan,Canada und U.S. in one single certification pro-cedure. **Relevant for:** Medical Device Manufacturers, having customers in countries/ markets, participating in MDSAP Program.

Further certifications and registrations in close cooperation with the DQS Group

- u. a. ISO 14001, ISO 50001, ISO 45001, ISO 27001, SCC/SCP, AZAV

Training, seminars, workshops

DQS MED ERFA-Club medical devices

Process audits

Contact us
or visit our homepage.

About us

DQS Medizinprodukte GmbH

- Independent and competent management partner for companies of all sizes and in all industries.
- In 1995, established as the DQS center of excellence for medical devices and designated as a notified body (identification number 0297) approved by the ZLG.
- Founded in 2008 as a wholly owned subsidiary of DQS Holding GmbH.
- Currently supervising by over 200 auditors and experts more than 1,600 customers with around 2,800 certified sites.
- Operating in the areas of medical device approvals and certification of management system in the health care markets for more than 25 years.

DQS Group

- More than 80 offices in over 60 countries.
- Approx. 25,000 customers currently representing approximately 65,000 certified sites in over 130 countries in almost all industries.
- Worldwide, approximately 3,000 employees, including around 2,500 auditors and experts.
- Is today one of the world´s largest system certification bodies.
- Other German subsidiaries of DQS Holding GmbH, headquartered in Frankfurt am Main:
  - DQS GmbH
  - DQS CFS GmbH

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Rev.: 03

Simply leveraging Quality.

ISO 13485:2016
Medical Devices – Quality Management
Regulatory Requirements

What are the changes between ISO 13485:2003 and 13485:2016?

The revised standard now covers the **Entire Lifecycle** and is explicitly applicable for **Outsourced Processes**. The **Regulatory Requirements** are no longer limited to the product design phase, but the complete scope of the QMS.
The concept of a **„Medical Device Family“** was introduced. **Software-Validation** was now clearly addressed. Some requirements, e.g. for **Design Transfer** and for **Sterile-Barrier-Systems** were included or extended, like for the **„Medical Device File“**.
Risk Management now covers a company-wide approach. Further on the standard demands to document the **Roles and Function(s)** of the organisation. More specific input and output aspects of **Management Reviews** were added, same as additional documentation requirements for the **Work Environment, Contamination Control** of sterile medical devices and labelling. The level of focus on **Reporting Procedures** was emphasized.

An ISO 13485 certified company

- gives evidence for regulatory compliance
- minimises and controls risks
- contributes to safety of patients and users
- underlines the competency of the organisation
- pursues failure prevention rather than correction
- improves quality of services
- improves satisfaction of customers and employees
- gives transparency and clarity of internal processes and
- reduces time and effort

Process Flow of QMS Certification

Procedural cycle takes 3 years

INFORMATION
Information meetings to discuss audit objectives, the certification process and the scope of the management system.

OFFER, APPLICATION and CONTRACT
Detailed offer specifying the scope of services and the time schedule in a transparent manner.

PRE-AUDIT (optional)
Auditing of selected areas or processes to improve certification propability.

SYSTEM ANALYSIS
Audit/assessment i.a. of the system documentation, the results of management review/internal audits, determining the time schedule and the details of the system audit on site.

SYSTEM AUDIT
Comprehensive auditing of the management system on site in order to assess the adequacy and efficiency of the management system and to establish conformity to the requirements of applicable standards. Presentation of the audit results/findings during the closing meeting. Required action plans will be agreed as necessary.

SYSTEM EVALUATION
Written report on audit results.

ISSUANCE OF CERTIFICATE
DQS MED assesses the results and decides independently on issuance of the certificate.

1st and 2nd SURVEILLANCE AUDIT
At least once a year, an audit of essential elements of the management system takes place on site.

RE-CERTIFICATION
Before expiration of the certificate, a new comprehensive audit and assessment of the system will take place to ensure conformity to the standard requirements.

New three-year cycle

EN ISO 13485 – potential customers?

The standard is dedicated to Medical Device Manufacturers demanded to meet both customer expectations and International, European or National regulatory requirements. Examples are Canadian, US-American or Japanese requirements as well as the European Directives and Regulations on Medical Devices and In-Vitro-Diagnostics. An ISO 13485 Certificate gives objective evidence for an organisation, that the Management System is compliant with the Standard.

Beside of Medical Device Manufacturers, ISO 13485:2016 can be applied from **Suppliers or external Parties**, providing **goods or services** for organisations producing Medical Devices.

DQS Medizinprodukte GmbH is accredited both from the German Accreditation Body (DAkkS) as well as from Standards Council of Canada (SCC) for ISO 13485:2016.

Comparison of ISO 13485:2016 with ISO 9001:2015

The High Level Structure, as known from the revised ISO 9001:2015 standard, was not adopted from ISO 13485:2016. Medical Device Manufacturers, striving for both ISO 13485 and ISO 9001:2015 certification have to be aware about the structural differences. On the other hand it is an advantage, that the new ISO 13485 kept the established structure.


CERTIFICATE

This is to certify that the company

Mustermann und Sohn GmbH & CO. KG

Musterstraße 1
47110 Musterhausen
Germany

has implemented and maintains a **Quality Management System.**

Scope:
Design, development, production and distribution of surgical instruments, dental instruments, endoscopes, endoscopic cameras, light source and light source cables, insufflators, units, non-active implants for osteosynthese, tonometers, wound clamps, aneurysm clips (permanent and temporary)