What else we can do for you

Certifications and accreditations on the basis of

- **ISO 9001** Standard applied and recognized worldwide 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.
- **Medical Device Directive 93/42/EEC** 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 procedure. **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

- **i.a.** ISO 14001, ISO 50001, BS OHSAS 18001, SCC/SCP; AZAV

Pre-submission meeting

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 for directive 93/42/EEC.
- Founded in 2008 as a wholly owned subsidiary of DQS Holding GmbH.
- Currently supervising more than 1200 customers with 150 auditors and experts.
- Operating in the areas of medical device approvals and certification of management system in the health care markets for more than 20 years.

DQS Group

- More than 80 offices in over 60 countries,
- Approx. 25,000 customers currently representing approximately 75,000 certified sites in over 130 countries in almost all industries
- Worldwide, approximately 2,800 employees, including about 2,300 auditors and experts
- Today it counts to one of the world's largest certification bodies
- Other German subsidiaries of DQS Holding GmbH, headquartered in Frankfurt am Main
  - DQS GmbH
  - DQS Food Safety Solutions GmbH

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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.

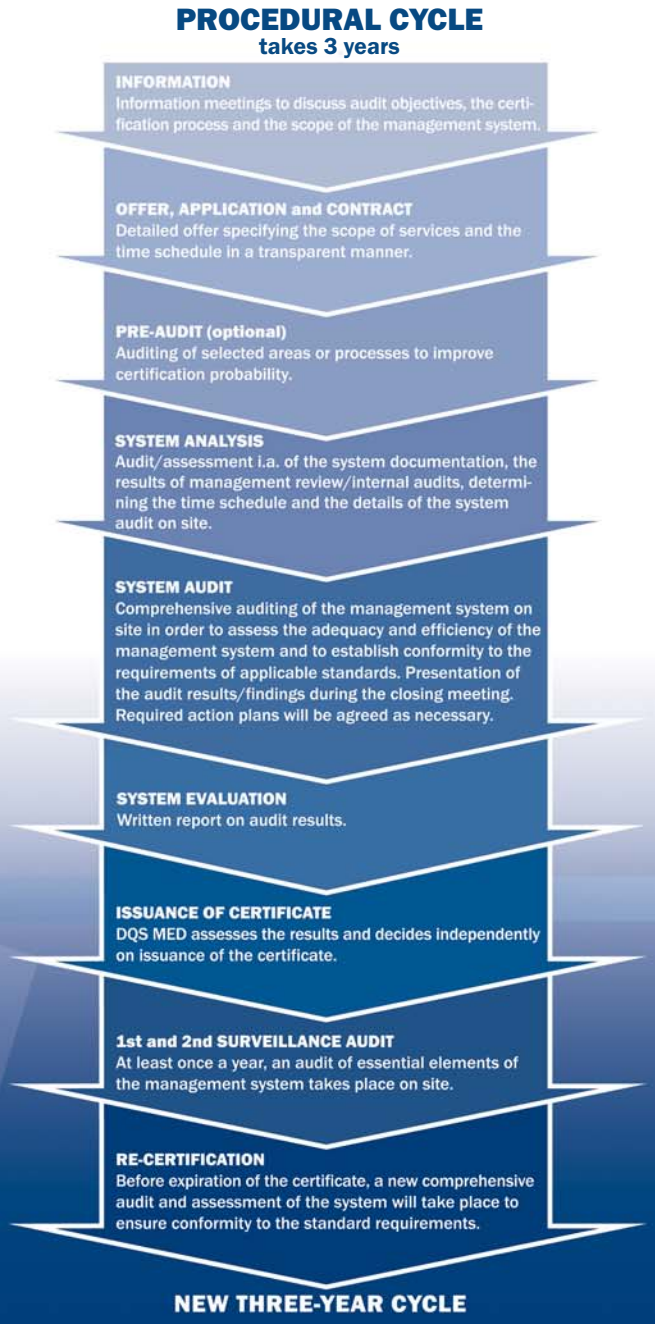
The concept of a **„Medical Device Family“** was introduced. **Software-Validation** was now clearly addressed. Some requirements, e.g. for **Design Transfer** and for **Sterile-Barrier-Systems** were included or extended, like for the **„Medical Device File“**.

Risk Management now covers a company-wide approach. Further on the standard demands to document the **Rolls 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 customer and employees
- gives transparency and clarity of internal processes and
- reduces time and effort

Process Flow of QMS Certification



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.