What else we can do for you

Certifications and accreditations on the basis of

- **ISO 13485** Process-oriented, industry-specific standard based on ISO 9001 with further requirements concerning safety and traceability. **Relevant for:** Manufacturers, distributors and service providers in the medical devices sector.
- **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.

Further certifications and registrations in close cooperation with the DQS-UL Group

- **i.a.** ISO 14001, ISO 50001, TS 16949, BS OHSAS 18001, SCC/SCP; AZAV

Pre-submission meeting

Training, seminars, workshops

DQS-MED ERFA-Club medical devices

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 100 auditors and experts-.
- Operating in the areas of medical device approvals and certification of management system in the health care markets for 20 years.

DQS-UL Gruppe

- More than 80 offices in over 60 countries,
- Approx. 20,000 customers currently representing approximately 47,000 certified sites in over 100 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-UL Food Safety Solutions GmbH

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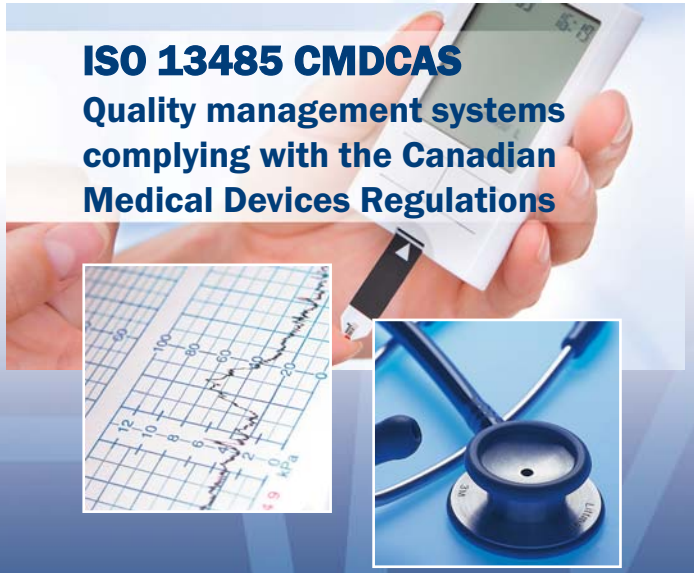
Rev.: 02

DQS MED®



ISO 13485 CMDCAS

Quality management systems complying with the Canadian Medical Devices Regulations

www.dqs-med.de

Principles and Significanc

In Canada, manufacturers of medical devices of classes II, III and IV according to the Canadian Medical Devices Regulations must hold licences. You can apply to the Canadian authorities for such a licence only if you hold a certificate of conformity to ISO 13485 recognized in accordance with the Canadian Medical Devices Conformity Assessment System (CMDCAS).

DQS MED is one of the few certification bodies worldwide authorised to issue certificates of conformity to ISO 13485 in accordance with the requirements of the CMDCAS. Since October 2003, DQS MED is accredited and listed by the Canadian accreditation authority Health Canada as a CMDCAS recognized registrar.

Use of CMDCAS Certification

Manufacturers also benefit from such certification according to ISO 13485 to demonstrate their competitive strength and efficiency in the national and international markets and to enhance their public reputation. A CMDCAS certified manufacturer

- is able to effectively implement the Canadian regulations concerning medical devices,
- ensures that the products, components and services purchased from suppliers have the required quality,
- minimizes and controls risks,
- emphasizes the competence of the enterprise,
- prevents errors instead of correcting them,
- improves the quality of performance,-
- provides transparency and clarity of internal processes, and
- saves time and costs.

The ISO 13485 CMDCAS Certification Procedure

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 safety.

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 certificat.

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

ISO 13485 – for whom?

ISO 13485 is an international standard that is recognized worldwide and is addressed above all to the manufacturers of medical devices. The manufacturers are obliged to prove that they fulfill any applicable legal requirements. By compliance with ISO 13485, the legal requirements of most industrial countries applying to quality management systems can be fulfilled.

For manufacturers of medical devices of classes II, III and IV who want to get their products licenced in Canada and sell their products on the Canadian market, CMDCAS certification is indispensable.

This applies to all manufacturers of products meeting the Canadian definition of “medical device”, even if these products are not considered medical devices in their country of manufacture (e.g., electrical toothbrushes, some electrical cigarettes).