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 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.

Further certifications and registrations in close cooperation with the DQS Group

- i. 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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Simply leveraging Quality.

Medical Device Single Audit Program (MDSAP)

Quality management systems complying with international medical device regulations

Principles and Significanc

The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

MDSAP should be considered for companies based globally, if they wish to sell products into the countries participating:

- The Australian Therapeutics Goods Administration (TGA) will use an MDSAP audit report as part of the evidence that is assessed for compliance with medical device market aut horization requirements unless the medical device is otherwise excluded or exempt from these requirements.
- The Brazilian National Health Surveillance Agency (ANVISA) will utilize the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures.
- Health Canada (HC) will exclusively accept MDSAP audit outcomes as part of their Canadian Medical Device Conformity Assessment System (CMDCAS) certification program for class II, III and IV medical device licenses, to prove regulatory compliance with quality management system requirements in Canada.
- U.S. Food and Drug Administration's Center for Devices and Radiological Health (FDA) will accept the MDSAP audit reports as a substitute for FDA routine inspections. Additionally, certification documents stating compliance with applicable US regulations may provide a marketing advantage.
- The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) will utilize these audit reports in both premarket and periodical post market audits under regulations in Japan.

The MDSAP 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 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

MDSAP – for whom?

The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions.

Your benefits, a single Audit will:

- minimize disruptions for medical device manufacturers due to the increasing number of regulatory audits and inspections
- incorporate ISO 13485 audit requirements, including regulatory requirements of participating jurisdictions (Australia, Brazil, Canada, Japan, USA)
- provide predictable audit schedules and outcomes
- reduce expenses in time and resource dealing with findings from multiple audits
- benefit patient health and patient access with ease of entry to multiple international markets
- improve transparency in the industry