What else we can offer you

Certifications and registrations 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.
- **MDSAP** With a MDSAP certificate, recognized by the Canadian authorities, evidencing conformity to ISO 13485, manufacturers of medical devices of classes II, III and IV according to the Canadian Medical Devices Regulations (CMDR), can obtain the license for the Canadian Market. **Relevant for:** Manufacturers of medical devices oriented towards the Canadian market
- **ISO 9001** Globally applied and recognized standard for ensuring the quality of processes and the results to improve the competitiveness factor. **Relevant for:** Every enterprise. The standard has a high level of recognition in healthcare and health-related social systems.
- **ISO 15378** is based on ISO 9001 and additionally comprises all GMP (Good Manufacturing Practices) requirements relevant for primary packagingmaterials. **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

Office Tuttlingen
Königstraße 13
D-78532 Tuttlingen
Tel. +49 7461 1617460

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
D-60433 Frankfurt am Main
Tel. +49 69 95427-300
Fax +49 69 95427-388
med@dqs.de
www.dqsglobal.com

Rev.: 02

Simply leveraging Quality.

Certification according to Medical Device Directive **MDR (EU) 2017/745**

Principles and Significance

Within the European Economic Area, medical devices have to be CE marked, before placed on the market. The CE-marked medical device must fulfil the essential requirements of the European Medical Device Regulation concerning safety and performance as documented in the framework of the conformity assessment procedures. These procedures and their implementation are layed down in the Medical Device Regulation (EU) 2017/745 and its Annexes. Depending on the risk classification of the product, conformity is either confirmed by the manufacturer in his own right, or by involving a Notified Body.

The type of the conformity assessment procedure and the extent to which an independent assessment and certification body (Notified Body) must be involved, depends on the potential risks associated with the product. While there is no further differentiation in the risk class of active, implantable medical devices, Annex VIII of Regulation (EU) 2017/745 provides a grouping of devices into 4 classes (I, IIa, IIb, III) and the applicable rules for classification.

Notified bodies carry out the related system assessments as well as product examinations and issue the corresponding certificates. DQS MED is a notified body of the European Union and as such authorised to perform conformity assessments according to Regulation (EU) 2017/745, which are mandatory for all Medical Devices, regardless if produced in or imported into the EU. We carry out conformity assessment procedures according to EU Regulation Annexes IX and XI/A and review the technical documentation for conformity to the requirements of the EU Regulation Annexes II and III.

Transitional period: As of 26 May 2021, Directive 93/42/EEC will cease to apply in relation to a Notified Body.

Unannounced audits: In accordance with recommendation 2013/473/EU, unannounced audits will be carried out annually or at least every three years.

Document language: DQS MED only accepts German and/or English language documents for procedures according to Regulation (EU) 2017/745.

MDR (EU) 2017 / 745

Certification procedure

INFORMATION
- Public Information
- Contacting DQS MED

QUOTATION + APPLICATION FOR CERTIFICATION
- Pre-Evaluation of your Application
- Application
- Application review

AUDIT
- Detailed Planning of the Customer Procedure
- Technical File Review | Stage 1
- Updating Planning, Supplementing Audit Objectives
- System Assessment
- System Evaluation (Report)

CERTIFICATION DECISION MAKING
- Final Review
- Certificate Issuance

You can find more detailed information on the certification process on our homepage, please see:
Regulation MDR (EU) 2017/745

Regulation 2017/745 – for which customers?

Before you place a medical device on the Europea market or put it into operation, your medical devices must be CE marked. A medical device describes an object or a substance used for medical, therapeutic or diagnostic purposes for human beings, whereby the intended main effect, in contrast to medicinal products, is not primarily pharmacological, metabolic or immunological, but physical or physicochemical. The CE mark is not a quality mark and is not intended for consumers. It is a legally binding statement by the manufacturer that his product meets all legal requirements.

Benefits of a medical device CE-certification:

The CE-certification by DQS-MED enables you to further exploit potentials, both in developed markets as well as to enter new national and international markets with the associated assessments of the devices and the Quality Management System, conforming to regulations. The certification will not only give you a clear competitive edge, but will also help to mitigate Risks and reduce liability obligations.