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.
- **MDSAP** With a MDSAP certificate evidencing conformity to ISO 13485 recognized by the Canadian authorities, 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** 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.
- **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, 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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Rev.: 04

DQS MED®

Directive 93/42/EEC
of the European Council concerning medical devices

www.dqs-med.de

Principles and Significance

In principle, medical devices are required to be CE marked before being first brought into market within the European Economic Area. The CE-marked medical devices must fulfill the essential requirements of European law governing medical devices as to safety, efficiency and innocuousness to human health and this must be documented in writing within the framework of conformity assessment procedures. The conformity assessment procedures and their implementation are specified in the Medical Devices Regulation (MPV) which refers to the relevant annexes to the European directives. Depending on the risk classification of the product, conformity is assessed and proven by the manufacturer in his own responsibility or by involving a notified body.

The type of conformity assessment procedure to be carried out and the extent to which an independent testing and certification body (notified body) must be involved will depend on the potential risks associated with the products. While no distinction is made between active implantable medical devices according to risk levels, Directive 93/42/EEC (MDD) provides for a grouping of devices into 4 product classes (I, IIa, IIb, III). The classification and the choice of conformity assessment procedure to be applied to a product is effected according to the criteria set out in Annex IX of Directive 93/42/EEC.

Notified bodies carry out the prescribed inspections and issue the required certficates. DQS MED is a notified body of the European Union and as such is authorised to perform conformity assessments in accordance with EU directives that are mandatory for all products imported into the EU. We carry out conformity assessment procedures in accordance with Annexes II, V and VI of the Medical Devices Directive and review the technical documentation for conformity to the requirements of Directive 93/42/EEC.

In Germany, the Medical Devices Act (Gesetz über Medizinprodukte, MPG) regulates the medical devices market. It implements the European Medical Devices Directive 93/42/EEC into national law.

Product Authorization Procedure

93/42/EEC – for whom?

Before you place a medical device on the European market or first put it into service, your medical device needs to bear the CE marking. ‘Medical device’ refers to an object or substance that is used for human beings for medical, therapeutic or diagnostic purposes and which, in contrast to drugs, does not achieve its principal intended action primarily by pharmacological, metabolical or immunological means, but by physical or physicochemical means. The CE marking is not a quality mark nor is it intended for the consumer. It is a legally binding statement by the manufacturer that his product conforms to all legal requirements.

Use of CE Certification of Medical Devices

CE certification of medical devices by DQS MED allows you, having undergone the required examinations proving conformity of your devices to the relevant standards, to make better use of your potential in existing markets and to enter into new national and international markets. And in addition it will help you mitigate the risks and liabilities in the markets you have chosen.

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