

Our Experience For Your Success



Quality Management – The Basis for Safe Devices

Quality management systems (QM-Systems) are widely established in the medical device industry. Due to the fact that the products are used directly on the patient for the treatment of illnesses or injuries or used for diagnosis, they have to fulfil particular high quality levels.

This leads to the situation that for the majority of medical devices the implementation of a QM-system is part of the legal requirements. In other cases customer requirements or the need for optimizing internal processes and improvement of security with respect to product liability are reasons for the implementation and subsequent voluntary certification of a QM-system.

EN ISO 13485 – Quality Management Standards for Medical Devices

For the field of medical devices the standard EN ISO 9001, which can be universally applied in any branch, is amended by specific standards, which shall be used. The international standard ISO 13485 specifies the requirements of ISO 9001 for medical devices and is a worldwide recognized model for a QM-system in the medical device industry. While in Europe this standard has the status of a Harmonized Standard, some other countries (e. g. Canada and Australia) have included ISO 13485 completely into their legislation and further countries (e. g. United States and Japan) have quality system requirements, which are similar to ISO 13485. For Europe using EN 46003 is an alternative for companies, which have implemented a QM-system for the final inspection and testing of their products only. This is useful only for areas where all relevant properties of the product can be verified in final quality control.

EN ISO 9001

If a company performs beside the manufacturing and maintenance of medical devices further activities for other branches or if respective customer requirements are existing, an additional certification according to the traditional standard ISO 9001 may be useful. This may be also an alternative for service providers in the area of medical devices if their activities do not directly influence the quality of the product.

For organizations in the health care sector like doctors practices, hospitals or nursing services ISO 9001 is the standard of the choice.

Good Reasons for a Voluntary Certification

For companies, which are not subject to certification by law there are quite good reasons for a voluntary certification according to ISO 13485 by a registrar, which acts also as a Notified Body. Suppliers of components and semi-finished devices as well as subcontractors and service providers will not only enjoy more confidence by their clients but can usually avoid multiple audits by the Notified Bodies of their different customers. In the context of a certification according to ISO 13485 Notified Bodies may confirm that certain technical standards (e. g. validation standards for sterilization) are fulfilled.

Manufacturers of custom made devices and class I medical devices (non sterile, no measuring function) as well as manufacturers of in vitro diagnostic devices, which are not for self-testing and are not listed in Annex II of Directive 98/79/EC are not subject to certification by a Notified Body by law. However, especially these companies have extensive legal requirements for documentation, which may be easily fulfilled with an implemented quality system. In this area, which includes professions like orthopaedic technicians, dental technicians and hearing aid technicians, their customers and in particular health insurances have increased their demands for certificates according to ISO 13485.

mdc medical device certification GmbH **Experience and Competence**

Under Directive 93/42/EEC for medical devices as well as under Directive 98/79/EC for in vitro diagnostic devices mdc was one of the first German Notified Bodies (identification number 0483). From the beginning we achieved a good reputation due to comprehensive and professional services for our clients.

After our merger with the Notified Body of ZDH-ZERT e. V. we have further developed our activities. In the meantime we serve more than 1000 clients in the medical device field and are among the big registrars in this branch not only for Germany but for whole Europe. With our staff of approx. 20 employees and 50 freelance auditors and experts we are in a position to provide certifications for a broad range of products and for companies of all sizes.

Accreditation

As Notified Body we offer for a comprehensive product range in the field of medical devices and in vitro diagnostic devices the certification services, which are legally required for manufacturers.

In the field of ISO 13485 there are only a few registrars, which are accredited by the Competent Authority ZLG (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten) and have in parallel the position of a Notified Body with a long experience in this specific sector.

For ISO 13485 we have a comprehensive accreditation scope, which covers active and non-active medical devices as well as for in vitro diagnostic devices.

We are accredited by TGA (Trägergemeinschaft Akkreditierung) for the certification according to ISO 9001 covering a broad scope of branches.

International Registrations

With the increasing globalization the markets of our clients are getting bigger and as a specialist in certification of medical devices we have to respond to this challenge. We are one of the few European Notified Bodies, which are recognized in Taiwan. Furthermore, we provide to our clients services for registration in Canada and Japan through cooperations with registrars accredited in the respective countries.

Information

The legal and normative requirements in the medical device sector are of a complex nature and need a lot of explanation. Therefore we offer interested companies and our clients detailed information. We provide information brochures about CE marking of medical devices and in vitro diagnostic devices, which explain the requirements of the Directives in a condensed format. We are ready to meet companies, which are interested in CE-marking of their medical devices already at an early stage in order to discuss the most suitable procedure for conformity assessment.

Furthermore, we perform regularly public seminars, which explain the complex requirements in the field of quality management and medical devices in detail. Updated information is provided on our website.



Legal Requirements

Manufacturers, as defined by law, are companies, which place products under their own name on the market. For the following devices they are subject to a third party certification by a Notified Body:

- medical devices according to Directive 93/42/EEC class I (sterile), I (with measuring function), IIa, IIb and III
- in vitro diagnostic devices for self-testing or listed in Annex II of Directive 98/79/EC
- active implantable medical devices according to Directive 90/385/EEC.

Depending on the products the aforementioned Directives allow different routes for the conformity assessment. Usually the certification of the quality system with an additional assessment of product related data is preferred. Only in a few cases the alternative routes via product testing by the Notified Body are selected.

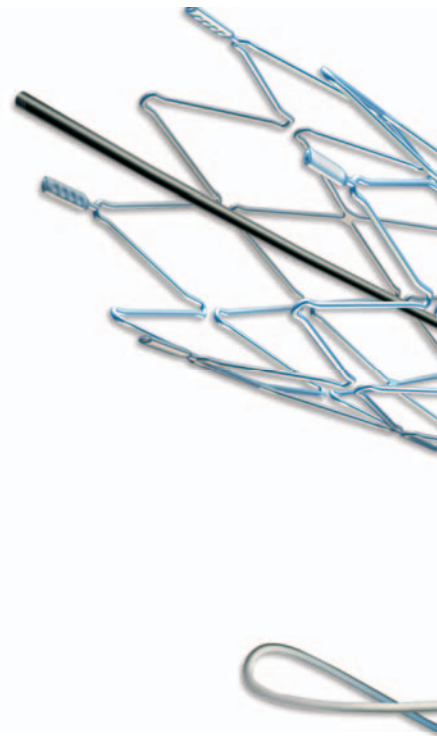
EU-Directives can not be directly used but they are transposed into national legislation of the EU member states, which the manufacturers, importers, authorized representatives and Notified Bodies are subject to.

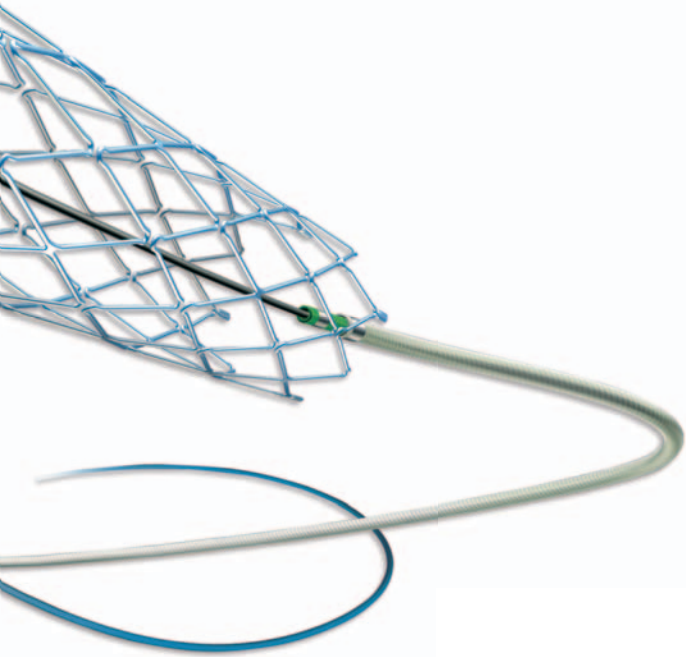
Notified Bodies

In case a certification for medical devices is part of the legal requirements, the certificate has to be issued by a Notified Body. Notified Bodies may be public or private entities and have to be approved and are under surveillance by Competent Authorities. Notified Bodies are assigned by the EU member states and notified to the EU Commission. They are published in the Official Journal of the European Union with their scope of activities and their 4-digit identification number.

CE Mark

In case of compliance with the respective EU Directive the manufacturer issues a Declaration of Conformity and affixes the CE mark on the products. On devices which require certification by a Notified Body, the CE mark is amended by the identification number of the Notified Body, which performed the certification according to the EU Directive. Products with CE mark may be shipped and placed on the market throughout the European Economic Area.





Certification of Medical Devices

The classification of medical devices determines the extend of involvement of a Notified Body in the conformity assessment procedure.

For medical devices class I (sterile) and class I (with measuring function) usually a certification of the quality system with respect to sterilization and maintenance of sterility or securing the measuring function is performed. In case of medical devices class IIa and class IIb usually a comprehensive certification of the quality

system is chosen. This does not only include a product related on-site audit but in addition an assessment of the technical files on a sampling basis.

For class III devices very often the route of a quality system in design, manufacturing and final inspection in combination with the EC-Design Examination is chosen. This contains a full assessment of the Technical File regarding complete compliance with the current state of the art.

Certification of In Vitro Diagnostic Devices

In case of in vitro diagnostic devices the category determines the extend of involvement of a Notified Body in the conformity assessment procedure.

Products for self testing, which are not listed in Annex II of Directive 98/79/EC are usually certified via an EC-Design Examination, which is a full assessment of the Technical File of every product type. Alternatively they can be treated like devices according to List B of Annex II, where the certification of the quality system in design, manufacturing and final inspection is selected. This is always combined with the assessment of the Technical Files on a sampling basis.

Devices according to List A of Annex II may be also certified via the full quality system as described before, but in addition the detailed examination of the Technical Files for each type (EC-Design Examination) is required. For List A devices a batch related verification of the manufactured products by the Notified Body is required.





mdc medical device certification GmbH

Kriegerstraße 6 · 70191 Stuttgart · Germany

Phone +49-(0)711-253597-0 · Fax +49-(0)711-253597-10

E-Mail: mdc@mdc-ce.de · Homepage: www.mdc-ce.de