medical device certification
mdc






FOR SAFETY AND QUALITY.

www.mdc-ce.de

OUR COMPANY.

"mdc medical device certification" stands since years for quality and safety in the sensitive field of medical devices and healthcare.

Around 100 employees and just as many external auditors, assessors and experts contribute to this. They ensure that, as a Notified Body in the field of medical devices and in-vitro diagnostics, and as an accredited certification body for QM systems and prequalifications, we are one of the well-known providers not only in Germany but also in Europe. The comprehensive expertise of our employees enables us to offer certifications for a wide range of products and services as well as for companies of all sizes.

At the time mdc was founded in 1994, we were one of the first Notified Bodies in Germany to be designated according to the European Medical Devices Directive 93/42/EEC and thus able to operate in the area of CE marking of medical devices. From the beginning, we have been auditing and certifying QM systems based on international standards.

Since then, we have continued to expand our sevices, focusing on our core competencies of medical devices, in-vitro diagnostics and healthcare. In addition to the constant expansion of our portfolio, the merger with ZDH-ZERT e. V. was a milestone in our history, because it formed the basis for constant growth. Other important milestones in our history include the opening of our Berlin office in 2010, the establishment of the austria branch in Vienna in 2016 and the Tuttlingen office in 2019.

More than 1.500 customers in Germany, Austria and around 30 other countries trust our knowledge and our service. Their customers and contractors rely on our certificates and products bearing the CE mark in conjunction with our identification number "0483". With our work, we not only make an important contribution to the safety of patients and users of medical devices, but also sustainably promote the idea of quality in the economy.

In addition to our competence and reliability, the cornerstones of our activities are independence, objectivity, neutrality and confidentiality.

AREAS OF COMPETENCE.

- **Medical devices**
- **Health Trade**
- **Medical Trade**
- **Health facilities**
- **in-vitro diagnostics**
- **and related areas**

OUR SERVICES.

We consider ourselves as a specialist supplier in the field of medical devices and healthcare as well as related areas. Our range of services in the field of assessment and certification is based on the needs of our customers since the beginning and will be expanded accordingly.

The assessment and certification of QM systems are our main activities. In the field of CE marking, we cover a wide range of products under the directives 93/42/EEC for medical devices and 98/79/EC for in-vitro diagnostics. The QM certifications we offer include various QM standards. In addition to the industry-specific standard EN ISO 13485 for medical devices, we also offer certifications according to the generally applicable EN ISO 9001.

In the field of the provision of medical aids, we are active as a DAkkS-accredited prequalification body, which carries out the prequalification procedure according to §126 SGB V (German Social Act).

We are one of only a few bodies in Europe whose audits are recognized in Taiwan.

For companies that want to use the MDSAP (Medical Device Single Audit Program) we offer audits in cooperation with a recognized auditing organization.

In addition, we offer tests according to other standards (e.g. QVH seal of quality and QVH ConformCert).

Our comprehensive offer is supplemented by the organization of public seminars. They offer employees of our customers and all other interested parties the opportunity to deepen their knowledge in the field of quality management and in regulatory affairs and keep it up to date.

AUTHORIZATION.

Notified Body according to Directive
- 93/42/EEC
- 98/79/EC

Applicant for designation under MDR and IVDR

Audit execution according to MDSAP

Accredited certification body for
- EN ISO 13485
- EN ISO 9001

Accredited prequalification body according to SGB V

Recognition in Taiwan (TCP)

QVH:
- seal of quality
- ConformCert

MEDICAL DEVICES.

The application and technology of medical devices is extremely diverse and continues to evolve dynamically. Medical devices improve the quality of life and can save lives. In order to ensure safety and performance, not only specific legislation but also separate quality standards have been established for medical devices.

Reliable safety and performance of the products are essential for patients and users, due to the fact that the patients rely on the product and often have no freedom of choice. This situation places particularly high demands not only on the manufacturers, suppliers and service providers involved, but also on the certification bodies that carry out conformity assessments in this area.

For manufacturers, we perform the certification procedures required for CE marking of devices in accordance with Directive 93/42/EEC as Notified Body (EU identification number "0483"). Conformity assessment procedures involving a Notified Body are mandatory for all manufacturers of series products, with the exception of Class I products (non-sterile, no measuring function). The main focus of our work is the review of the QM system at the manufacturer's premises and its subcontractors as well as the review of the technical documentation of the affected products. In addition to industry experienced auditors, we have a large number of experts with many years of experience in industry, hospitals, testing laboratories or Notified Bodies.

A voluntary certification according to QM standards represents a real benefit for manufacturers of medical devices of all risk classes, but also for suppliers of components and semi-finished products as well as for contract manufacturers and service providers. Manufacturers receive an assessment of their QM system against the background of regulatory requirements. For many suppliers and service providers, manufacturers practically require the availability of a certificate according to EN ISO 13485. In addition, the certificate of an accredited certification body, which is also Notified Body for medical devices, clearly reduces the probability of subcontractor audits by Notified Bodies.

We offer manufacturers with the target markets Australia, Brazil, Japan, Canada or USA MDSAP audits in cooperation with a recognized "Auditing Organization".

For the new Medical Device Regulation (EU) 2017/745 (MDR) we are applicant for designation.

OUR SERVICES.

Certification according to

- Directive 92/43 / EC
- EN ISO 9001
- EN ISO 13485

- Applicant for designation under MDR

Audits for

- Taiwan
- MDSAP

Seminars

SERVICE PROVIDER IN HEALTH CARE AND TRADE.

As a company belonging to the craft organizations, we feel particularly committed to the crafts. We offer services that are tailored to the needs of health trade and meet the requirements of these businesses. Large parts of the supply with medical aids are performed by qualified retailers. They are subject to special requirements, which can be reasonably determined and controlled in the context of a QM system.

Healthcare companies, service providers, distributors and custom made medical device manufacturers are supported in meeting their legal obligations and in the definition of processes by implementing a QM system. The certification of this system by mdc is not only a benefit for the image in public, but also supports the development of the companies. Trained and experienced auditors are available for conducting the audits. Our employees are qualified to interpret the requirements of the QM standards in a practice-oriented and appropriate manner and to cultivate a partnership approach as equals.

For companies that are service providers for health insurance companies within the scope of the aid supply, we carry out the prequalification in accordance with § 126 SGB V. Prequalification by a DAkkS-accredited certification body is a prerequisite for concluding supply contracts with health insurances. In the prequalification procedure, proof for the fulfillment of organizational, professional, spatial and material prerequisites are checked. In addition to verifying written evidence, this procedure also includes on-site assessments performed by our experienced assessors.

For sector-specific quality assessments or quality seals, we are available as an independent partner. Thus, we are assessment audit body for the "Qualitätsverbund Hilfsmittel e.V." within the framework of the QVH Quality Seal and also acknowledged for the QVH ConformCert model.

In addition, we also offer specific seminars in the field of quality management for health care service providers.

OUR SERVICES.

Certification according to

- EN ISO 13485
- EN ISO 9001
- QVH ConformCert

Prequalification according to SGB V

Examination for the QVH seal of quality

Specialist seminars

IN-VITRO DIAGNOSTICS.

A particular group of medical devices are in-vitro diagnostics. Although they are not applied directly to humans, but only to samples from the human body, they can have a special hazard potential due to their often critical purpose and their use in a high number of examinations.

For manufacturers of in-vitro diagnostic medical devices, we carry out the certifications required for the CE marking of the products in accordance with Directive 98/79/EC as a Notified Body (EU identification number "0483").

Notified Body Conformity Assessment Procedures are mandatory for all manufacturers of List A and B products in accordance with Annex II of Directive 98/79/EC, as well as for all self-testing devices for lay users. The focus of our activities is the audit of the QM system at the manufacturer's premises and its subcontractors as well as the review of the technical documentation for the respective products. Auditors and experts with many years of experience in industry, research institutes, laboratories or Notified Bodies are at our disposal. For the compulsory verification of manufactured batches of products listed in Annex II, List A, we are cooperating since many years with the testing laboratory for in-vitro diagnostics of the Paul-Ehrlich-Institute.

Voluntary certification according to QM standards is also of particular importance for manufacturers of in-vitro diagnostics. In the case of in vitro diagnostic medical devices not subjet to certification requirements manufacturers receive an assessment of their QM system against the background of regulatory requirements. In addition to the fact that many manufacturers now require proof from their suppliers of an effectively introduced QM system, such certificates can be taken into account by accredited certification bodies who are also notified bodies.

We offer manufacturers with the target markets Australia, Brazil, Japan, Canada or USA MDSAP audits in cooperation with a recognized "Auditing Organization".

We have decided to be one of the few European bodies seeking a designation under the new Regulation (EU) 2017/746 (IVDR).

OUR SERVICES.

Certification according to

- Directive 98/79/EC
- EN ISO 9001
- EN ISO 13485

Applicant for designation under IVDR

Audits for

- Taiwan
- MDSAP

HEALTH CARE.

Healthcare providers have a quality assurance obligation under the German Social Act. Thus, in institutions such as medical practices, pharmacies, hospitals, care services or rehabilitation facilities, the introduction of QM systems has been established.

The increasing obligations to provide evidence to patients and health insurances as well as the often close cooperation of various service providers who are involved in patient care have intensified this development. Healthcare facilities are not subject to any statutory certification requirement. However, with the certificate of an accredited certification body, the introduction of the QM system can be effectively presented both in public and internally.

In health care the application of the international standard EN ISO 9001 was established along with other specific, mostly national certification systems.

Individual areas of health care facilities, such as the trade in medical devices, the reprocessing of surgical instruments or orthopedic workshops in clinics, are also covered by the scope of EN ISO 13485. We offer our expertise also in this area.

A variety of Auditors are available to carry out audits. Based on their experience in hospitals, medical practices and other health care institutions, they are able to interpret the requirements of QM standards in a practice-oriented and appropriate manner.

OUR SERVICES.

Certification according to

- EN ISO 13485
- EN ISO 9001
- QVH ConformCent

Prequalification according to SGB V

Specialist Seminars

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