

Basic Information about the European Directive 93/42/EEC on Medical Devices



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>

PREFACE

This booklet is intended to provide an introduction to the principles of European 'New Approach Directives' and in particular of the Medical Device Directive 93/42/EEC (MDD). Its purpose is to help medical device manufacturers to understand and comply with the MDD and CE-marking requirements. Numerous discussions with clients, auditors and experts were the basis for constructing this booklet.

The booklet is divided into individual chapters - each designed to be self-contained - and includes references to further supporting documents.

Such a brief introduction can never replace the detailed study of legal text. Here we would like to draw your attention to the MEDDEV documents and Notified Bodies Medical Device (NB-MED) Recommendations which contain the results of various working groups established by the European Commission.

Although mdc is always close to these working groups we cannot guarantee for the accuracy of the information provided.

Stuttgart, Germany, May 2004

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CONTENTS

CE-MARKING: THE PRINCIPLES OF EUROPEAN DIRECTIVES	4
NOTIFIED BODIES.....	5
MDD: THE MEDICAL DEVICES DIRECTIVE 93/42/EEC - INTRODUCTION	6
MEDICAL DEVICE CLASSIFICATION	8
QUALITY SYSTEMS: ISO 9000 - ISO 13485 – CE-MARK	9
TECHNICAL FILES - RISK ANALYSIS - HARMONIZED STANDARDS	10
THE EUROPEAN MEDICAL DEVICE VIGILANCE SYSTEM	11
HOW TO OBTAIN THE CE-MARK – STEPS IN THE CERTIFICATION PROCEDURE	12
MDC – NOTIFIED BODY 0483.....	18
FURTHER INFORMATION AND DOCUMENTS	19

CE-MARKING: THE PRINCIPLES OF EUROPEAN DIRECTIVES

The European Union (EU) includes the following 25 Member States: Austria, Belgium, Denmark, Estland, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, The Netherlands, Czech Republic, UK and Cyprus. These Member States differ in their constitutional and legal systems.

Where harmonization of legal requirements or administrative regulations is necessary, the European Commission -the executive body of the European Union- develops regulations, which after acceptance by the European Council, are called Council Directives or simply directives. Each directive describes the consensus that has been achieved and provides a deadline for the transposition of this consensus into the national laws of each Member State.

In 1985 a European Council Resolution on a new approach to technical harmonization and standards proposed a radical change in regulating the technical aspects of industrial products. The new approach involves the development of legislation specifying only the essential requirements that are general and mandatory. The detailed technical specifications that may be used to demonstrate conformity with the essential requirements are elaborated in voluntary harmonized standards.

Since 1st January 1993, the completion of the internal market has allowed free movement of goods throughout the territory of the European Union. A condition for such freedom of movement is the application of technical harmonization directives -also referred to as new approach directives- covering a wide range of industrial products such as machinery, personal protective equipment, medical devices, telecommunication terminal equipment, toys, in-vitro diagnostic medical devices and so on.

The conformity assessment of a product or family of products may require the certification by a Notified Body as regulated in the respective directive. Lists of Notified Bodies, the tasks and responsibilities which have been assigned to them, and their unique four digit identification number is published and updated in the Official Journal of the European Communities.

If certification is a requirement as part of the conformity assessment procedure, the manufacturer has the option to choose any of the Notified Bodies in any of the Member States of the European Union. If a product complies with the requirements of a new approach directive, the manufacturer marks it with the CE-mark. Products which require certification by a Notified Body carry the CE-mark in combination with the number of the Notified Body, for example:



NOTIFIED BODIES

The European new approach directives require the involvement of third parties in the conformity assessment of certain products. Traditionally these third parties had been national authorities of the Member States. However, some Member States had gained good experience in delegating technical work to non-governmental entities. These non-governmental entities were unknown to some Member States and to the European Commission. As there were no uniform criteria for the designation of such entities, the development of European legislation was relatively difficult.

The new approach reoriented EU legislative policy on such matters as technical competence, objectivity and transparency as the foundations for the necessary degree of trust in the system, on the basis of documented technical criteria enshrined in the legislation itself and in the appropriate European standards (i. e. EN 45000 series). Member States are invited under all new approach directives to notify the Commission of those bodies which they consider competent to undertake the responsibilities of Notified Bodies. A clear distinction shall be made at the national level between the Notified Bodies who intervene in the pre-market conformity assessment procedures and the national public authorities (national, regional or local) responsible for the market surveillance imposed by the directives for products on the market.

Notified Bodies are free to offer their conformity assessment services for which they are notified to any manufacturer established either inside the EU or in third countries. They may carry out these activities on the territory of other countries either with their own personnel or with subcontractors.

At the time of the first notification with respect to a new approach directive the EU Commission assigns a four digit identification number to the Notified Body. This number will not change when the same Notified Body is notified for other directives at a later stage.

Notified Bodies are under surveillance by their national notifying authorities which have the authority to withdraw or modify the notification as soon as the conditions of notification are no longer met.

Notified Bodies are and must remain third parties, independent of their clients and other interested parties.

With respect to the European Medical Devices Directive 93/42/EEC Notified Bodies are entitled to perform product as well as quality system management related conformity assessment procedures as outlined in Article 9 and the Annexes II, III, IV, V, VI and VII of this directive. Notified Bodies may have a limited scope with respect to the device families and/or the Annexes for which they are notified.

MDD: THE MEDICAL DEVICES DIRECTIVE 93/42/EEC - INTRODUCTION

There are three directives for medical devices:

- the Active Implantable Medical Device (AIMD) Directive - 90/385/EEC
- the Medical Device Directive (MDD) - 93/42/EEC
- the In Vitro Diagnostic Device Directive (IVD) - 98/79/EC.

The following exposition refers to the MDD, although most provisions are much the same under the other two medical device directives.

Under the MDD a 'medical device' is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

An 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

'Manufacturer' in the sense of the Medical Devices Directives means the natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

All medical devices must meet the applicable 'essential requirements' on safety, performance and labeling as outlined in Annex I of the MDD. Safety requirements are not restricted to patients but include users and, where applicable, other persons. The fulfillment of the essential requirements has to be demonstrated by the manufacturer for all devices whether they are new devices or whether they have already been on the market in former times. Under the MDD there are no provisions for a "grandfathering" approach as known for example in the US.

Labeling may be and in general is required by each Member State in its national language(s); the use of symbols is recommended.

Medical devices are classified in accordance with Annex IX of the MDD. The classification determines which conformity assessment procedure the manufacturer must follow in accordance with the Annexes II, III, IV, V, VI and VII of the MDD.

Regardless of the class a device belongs to, the manufacturer is obliged to maintain a 'technical file', for the respective device or device family. Moreover, it is his responsibility to issue and keep on file 'declarations of conformity' for his CE-marked devices. For custom-made devices and devices intended for clinical investigations the manufacturer must draw up a 'statement concerning devices for special purposes' according to Annex VIII.

As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances under normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on 'clinical data'. This applies in particular to implantable devices and devices in class III. According to Annex X, the clinical data must be based on:

- either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation;
- or the results of all the clinical investigations conducted.

For clinical investigations the rules laid down in Article 15 and Annex X of the MDD apply and the performance of clinical trials is recommended to follow the standard EN 540.

Here the Notified Bodies Recommendations NB-MED/2.7/Rec 1 'Guidance on clinicals' and NB-MED/2.7/Rec 3 'Evaluation of clinical data' are helpful.

MDD, Article 14.2 rules that, where a manufacturer without a registered place of business in a Member State of the EU places class I or custom-made devices on the EU market, he shall designate a 'responsible person' who is established in the Community (e.g. authorized representative). This person shall inform the 'Competent Authorities' of the Member State of the address of the registered place of business and the category of devices concerned. Furthermore the label or the outer packaging, or instructions for use shall contain in addition the name and address of either the responsible person or the authorized representative of the manufacturer established within the Community or of the importer established within the Community. These persons are also obliged to the duties concerning the storage of the 'technical file'.

Since 14 June 1998 no medical device covered by the MDD 93/42/EEC shall be placed on the market that does not carry a CE mark. 'Placing on the market' means making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view toward distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.

For 'putting into service' devices without CE-mark there is an extended transition period until 30 June 2001. Putting into service means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.

The only devices not requiring a CE-mark are 'custom-made devices' and 'devices intended for clinical investigations', where the manufacturer must keep documentation in accordance with MDD Annex VIII. Custom-made device means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

MEDICAL DEVICE CLASSIFICATION

According to the classification rules detailed in Annex IX of the MDD, medical devices and accessories are classified into one of the four classes I, IIa, IIb and III.

Rules 1 to 12 classify devices according to general criteria, particularly invasiveness, duration of continuous contact, nature of the tissue contact, and distinction between non-active and active devices.

The duration of continuous contact is transient (intended use < 60 minutes), short term (intended use ≤ 30 days) or long term (intended use > 30 days). Note: This schedule differs from the regimen defined in ISO 10993-1 for the biological evaluation of medical devices, where limited exposure means ≤ 24 hours, prolonged exposure means ≤ 30 days and permanent contact means > 30 days. Further ISO 10993-1 considers a cumulative exposure whereas the classification under the MDD considers only one single continuous use.

Devices applied in the oral or nasal cavity or the ear canal up to the ear drum are generally in lower classes. Devices in contact with the central nervous system, heart, or central circulatory system are in higher classes than devices in contact with other tissues.

Reusable surgical instruments which are not connected to an active device are in class I.

Implantable and long-term invasive devices which are intended to have a biological effect or be mainly absorbed or undergo chemical change in the body are in class III (rule 8).

For active devices, whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy, rules 9 to 12 apply.

The following special rules apply and override other rules if applicable:

- Rule 13: Devices incorporating as an integral part a medicinal product with ancillary action to the main intended action of the device are class III devices
- Rule 14: Devices for contraception or prevention of the transmission of sexually transmitted diseases are in class IIb, unless they are implantable or long-term invasive, in which case they are in class III
- Rule 15: Contact lens care products are in class IIb; other devices specifically intended for disinfecting medical devices are in class IIa
This rule does not apply for products intended to physically clean other products than contact lenses.
- Rule 16: Non-active devices specifically intended for recording X-ray diagnostic images are in class IIa
- Rule 17: Devices using animal tissues or derivatives rendered non-viable are in class III, except when in contact with intact skin only
- Rule 18: Blood bags are in class IIb

Detailed guidance on the classification of medical devices is provided in the document MEDDEV 2.4/1 (see the chapter Selected Directives and related Guidance Documents).

QUALITY SYSTEMS: ISO 9000 - ISO 13485 – CE-MARK

It can be recognized in the worldwide development of regulatory requirements for medical devices as well as for many other products that the introduction of quality systems is more and more requested. It is no secret that a suitable quality system, which is implemented in all relevant stages may be an important factor for maintaining and improving product safety and performance.

For whatever reasons, a lot of manufacturers persistently believe that a quality management system according to ISO 9001/2/3 is the key to CE-marking. This is simply wrong. The ISO 9000 series of standards is the most popular way for the proper organization of a quality management system. ISO 13485 under consideration of ISO/TR 14969 are another possibility. But harmonized standards are not the only way to demonstrate compliance with the MDD (see next chapter).

The MDD requires that the manufacturer of medical devices keeps a product-related, adequate and efficacious quality system. The application of the quality system must ensure that the products conform to the provisions of the MDD. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programs, quality plans, quality manuals and quality records.

The IVDD gives more flexibility to the device manufacturer in organizing his company according to size, social environment, culture of countries, and nature of the devices than the ISO 9000 series of standards. On the other hand even ISO 9001 in combination with the additional requirements of EN ISO 13485, under consideration of ISO/TR 14969, does not fully cover the requirements of the MDD.

Additional aspects to be covered by the quality management system include:

- the technical documentation
- reference to the essential requirements according to Annex I of the MDD
- information about harmonized standards and medical device regulations
- risk analysis
- labeling and instructions for use
- different languages
- post-marketing surveillance
- reporting under the vigilance system
- retention of certain documents

It is the task of the Notified Body to understand the culture of the manufacturer and to evaluate whether or not the quality management system meets the minimum requirements of the IVDD, and to give advice where deficiencies are detected.

Although the standards ISO 9001/2/3 from 1994 have meanwhile been replaced by ISO 9001:2000, they continue to be the basis for the harmonized standards EN ISO 13485, EN ISO 13488 and EN 46003. EN ISO 13485:2003, which is based almost completely on ISO 9001:2000, has been passed in June 2003 and has been published as EN ISO 13485:2003. This standard has, in contrast to EN ISO 13485/88 (2000), an independent content without references to ISO 9001, and deviates with respect to some requirements from ISO 9001:2000.

EN ISO 13485:2003 is a harmonized standard and the standards EN ISO 13485 and 13488 from (2000) were, until their withdrawal in the middle of 2006 equivalent as harmonized standards.

TECHNICAL FILES - RISK ANALYSIS - HARMONIZED STANDARDS

No matter whether the device is for clinical investigation, custom-made, class I, IIa, IIb or III, a technical documentation (device master file, technical file, design dossier) is always required. Particular requirements are given in the MDD, Annex II.3.2 (c) and 4.2, Annex III.3, Annex VII.3, and Annex VIII.3.1 and 3.2.

The recommended minimum content of a technical file is as follows:

- a table of contents
- manufacturer's declaration of conformity
- a general description of the device/device family, including any variants planned
- design drawings, specifications, methods of manufacture, including method of sterilization and validation data
- results of risk analysis
- results of calculations and test reports
- reference to applicable harmonized standards
- evidence that the essential requirements have been met
- clinical data
- label and instructions for use
- results of database researches and copies of relevant literature

Guidance is also given in the Notified Bodies Medical Devices (NB-MED) Recommendation document (NB-MED/2.5.1/Rec 5) 'Technical documentation'.

Raw material manufacturers or subcontractors may submit master files to the Notified Body, which can then be referenced in the technical file of the device manufacturer. Similarly producers of white label/OEM (Original Equipment Manufacturer) devices may submit documentation.

The MDD increases the responsibility of medical device manufacturers beyond previous regulations by strictly requiring a formal risk analysis for each device/device family. A preferred standard to be used is the harmonized standard EN 14971 about the risk management of medical devices.

In accordance with the new approach the EU Commission gives mandates and financial support to the European Standards Committee, CEN/CENELEC, for the development of standards for proving the compliance of products with the essential requirements of directives. After review whether or not the essential requirements are covered, the Commission decides about the publication of the reference of such standards in the Official Journal of the European Community. By publication of the reference these standards achieve the status of a harmonized standard. Manufacturers, who observe the harmonized standards are presumed, that their products are in compliance with relevant essential requirements (MDD, Article 5), too. Harmonized standards are still voluntary; where the manufacturer does not apply a harmonized standard he has to document the alternative solutions adopted to meet the essential requirements of the directive.

THE EUROPEAN MEDICAL DEVICE VIGILANCE SYSTEM

Article 10 of the MDD requires Member States to take the necessary steps to ensure that any information brought to their knowledge about

- any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead or have led to the death of a patient or user or to a serious deterioration in his state of health,
- any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to above, leading to a systematic recall of devices of the same type by the manufacturer

is recorded and evaluated centrally. Details of the medical device vigilance system and the necessary activities of the manufacturers, Competent Authorities, Commission, Notified Bodies, and users are regulated in the document MEDDEV 2.12/1: 'Guidelines on a medical device vigilance system'.

In contrast to the medical device reporting (MDR) system of the United States only serious and potentially serious problems with devices have to be reported in Europe. Similar to the MDR the European vigilance guideline asks for global reporting of incidents – no matter in which country they might happen.

The obligation of medical device manufacturers to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action is regulated in the conformity assessment procedures in the Annexes II, IV, V, VI, and VII of the MDD. The proper establishment of this post-marketing surveillance (PMS) system by the manufacturer is subject to the inspections by the Notified Body.

Where a Member State ascertains that medical devices, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision. The Commission shall consult, as soon as possible, with the parties concerned. Thus the safeguard clause in Article 8 of the MDD gives Member States the right to intervene immediately even in the case of devices correctly CE-marked, if there is an acute danger for the health of patients, users or third persons.

HOW TO OBTAIN THE CE-MARK – STEPS IN THE CERTIFICATION PROCEDURE

I. GENERAL

As mentioned in previous chapters the European Medical Devices Directives focus on the responsibility of the device manufacturers. Therefore CE marking for all medical devices requires among others a technical documentation, a risk analysis, a proof of compliance with the essential requirements of the directive and a product-related declaration of conformity issued by the manufacturer.

Only non-sterile class I devices without measuring function do not require the involvement of a Notified Body. The manufacturer of such devices marks them under his sole responsibility with the CE-mark without a number.

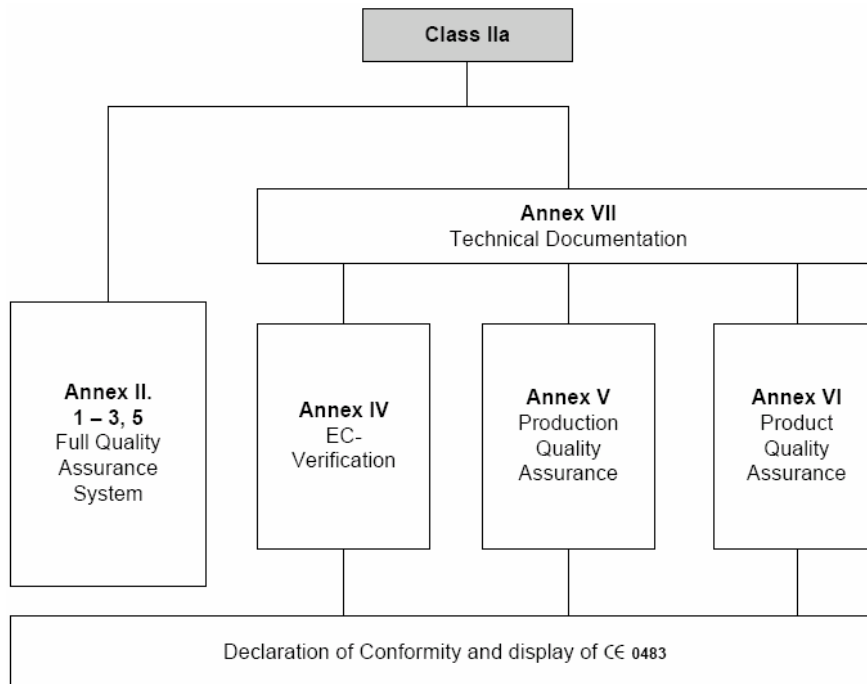
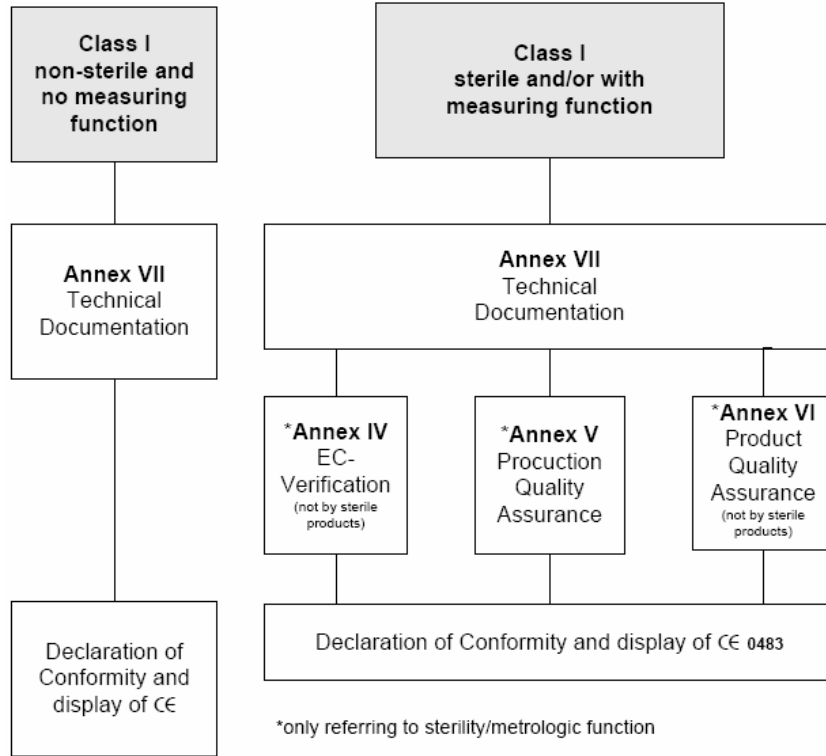
All other devices require the certification by a Notified Body before the manufacturer can put the CE-mark in combination with the number of the Notified Body on the device. Depending on the device class the manufacturer has the choice between different certification routes as graphically shown on the following pages.

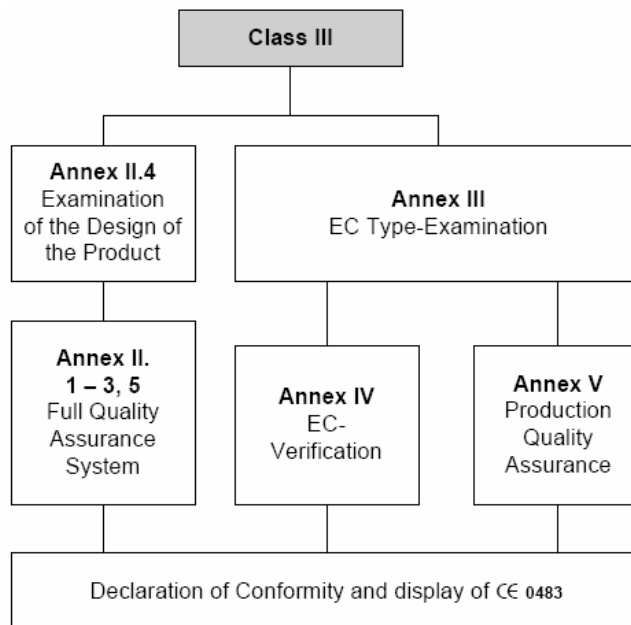
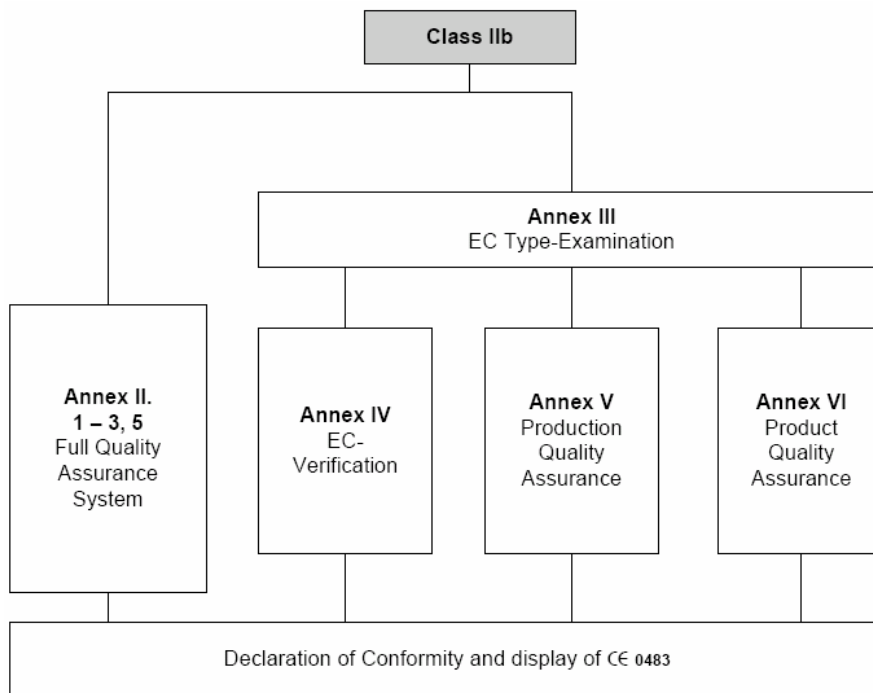
The certification usually includes the following steps:

- decision whether or not a product is a medical device and by which of the European Medical Devices Directives it is covered
- classification of the device(s) by the manufacturer
- contact to Notified Bodies, preliminary discussions and exchange of information, choice of the Notified Body
- answering of specific questions of the chosen Notified Body (usually by filling out a questionnaire provided by the Notified Body); confirmation of device classification by the Notified Body, time and cost estimation for different certification routes; choice of the certification route by the manufacturer
- formal application and certification contract
- submission of documents to the Notified Body
- evaluation of the submitted documents and report
- audit of the manufacturer's operations and if applicable and required also suppliers' and/or subcontractors' facilities including reporting
- decision about the certification and issuing of the relevant certificate(s), which are usually valid for five years
- surveillance audits (performed by mdc annually)
- full re-audit and issuing of a new certificate usually after five years

The following pages contain diagrams with the various certification routes and a brief description of Annexes II - VII of the MDD.

II. Conformity Assessment Procedures – (Annexes II to VII)





Annexes II – VII of the Medical Devices Directive 93/42/EEC (MDD)

Annex II – EC Declaration of Conformity (Full Quality Assurance System):

Most comprehensive conformity assessment procedure referring to a full quality system including the design phase for new devices or changes of existing devices; Section 4 (Examination of the Design of the Product) applies only to class III devices; this Section is similar to Annex III - EC Type-Examination with the difference that in-house test results obtained by the manufacturer under his full quality management system may be used as the basis of certification; the manufacturer may choose the harmonized standards EN ISO 13485:2003 in combination with the respective guidance standard as the basis of his quality system or use an equivalent quality system suitable to fulfill the requirements of the MDD.

Annex III - EC Type Examination:

A conformity assessment procedure for the product design which involves examination and third party testing of representative samples of the device and certification that the device meets the applicable essential requirements of the MDD; EC Type Examination is applicable only to class IIb and III devices.

Annex IV - EC Verification:

A conformity assessment procedure in which the Notified Body examines and tests every individual device or devices taken on a statistical basis, if the manufacturer manufactures homogeneous batches; the Notified Body releases individual devices or batches; EC Verification may be applied to class IIa, IIb and III devices.

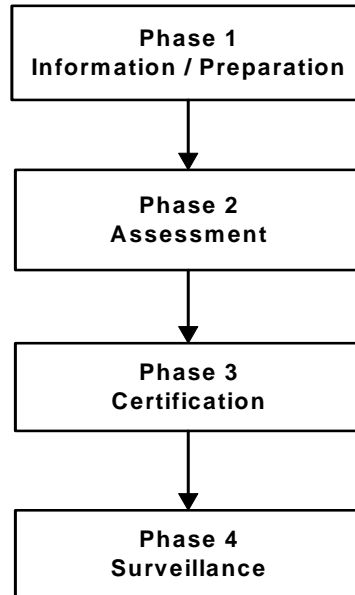
Annex V - EC Declaration of Conformity (Production Quality Assurance): A conformity assessment procedure for the quality system of the manufacturer excluding the design phase of new devices but including all other aspects of conformity with the MDD; this conformity assessment procedure is the most suitable procedure for sterile class IIa devices, if the manufacturer does not choose the Annex II as the basis of certification; it may also be applied to class IIb and III devices in combination with Annex III; the manufacturer may base his quality system on the harmonized standards EN ISO 13485:2003.

Annex VI - EC Declaration of Conformity (Product Quality Assurance): A conformity assessment procedure for the quality system for manufacturers of devices whose relevant properties can be assessed in final inspection; the manufacturer may base his quality system on the standard EN 46003; this conformity assessment procedure is not suitable for devices involving special manufacturing processes requiring validation, like sterilization; Annex VI may not be used for the assessment of class III products.

Annex VII - EC Declaration of Conformity: A conformity assessment procedure in which the manufacturer himself declares the compliance of his devices with the MDD; suitable for class I devices, and required for class IIa devices in combination with one of the Annexes IV, V, or VI.

III. Specific mdc-certification process

mdc divides the steps to obtain a certification in the following four phases:



Phase 1: Information / Preparation

Every project can only be as good as it is prepared. Therefore an exchange of information between the manufacturer and the notified body at an early stage is required. mdc always asks manufacturers to fill in a short questionnaire (see the last section of this brochure), which asks for data about the company and products. On the basis of this questionnaire and some accompanying information mdc is usually enabled to provide a detailed tailored proposal with respect to time and costs for the whole process. In addition mdc considers a personal meeting always as useful. In such a meeting questions like classification, selection of a suitable conformity assessment procedure can be treated and discussions about involved organizational and technical issues may facilitate a smooth further certification process. With the application of the manufacturer the certification process starts.

Phase 2: Assessment

To initiate the assessment phase mdc proposes the audit team to the applicant. The documentation is assessed by the proposed auditors and/or experts. In cases of quality system certifications an audit is always performed at the manufacturer's premises and if required at the premises of his subcontractors. The audit follows an audit schedule, which is agreed upon in advance with the manufacturer. The results of the assessment activities are reported in writing and the performance of necessary corrective actions is verified through a follow-up assessment.

Phase 3: Certification

After completion of the assessment the reports are handed over to mdc's certification board. This board reviews the results and verifies that the certification process so far meets the requirements. If the certification board can confirm compliance with the requirements a certificate will be issued. In case of a rejection mdc informs the applicant about the conditions for getting the certificate. The validity of certificates according to the MDD is usually for a period of 5 years.

Phase 4: Surveillance

To maintain certification for the full period of the validity, the manufacturer is subject to regular and, if necessary, extraordinary surveillances. Manufacturers, which hold a quality system certificate, usually undergo one surveillance audit per year. Planned changes in the organizational structure, manufacturing processes or products have to be reported and may cause additional surveillance activities and approval.

Before the expiry of a certification mdc starts again the process with the exchange of information for the renewal of the certification, which includes all aforementioned stages. The fact that mdc is already familiar with the company and its products results usually in reduced assessment expenditure in comparison to the initial certification.

Certification of Quality Systems

The above procedure applies as well to the certifications according to the voluntary standards ISO 9001, ISO 13485 and EN 46003. These certifications can be realized by mdc or together with accredited co-operation partners in a common assessment and certification process. mdc is accredited by TGA and ZLG respectively for the stated standards.

MDC – NOTIFIED BODY 0483

mdc is not a newcomer in the medical device business. In 1994 mdc was notified by the German Ministry of Health (Bundesministerium für Gesundheit) to the European Commission for conformity assessment procedures under the European Medical Device Directive 93/42/EEC as one of the first German entities. The Commission assigned us the identification number 0483 and listed mdc as Notified Body in the Official Journal of the EC.

Since 2000-10-01 mdc medical device certification GmbH and Zertifizierungsstelle Medizinprodukte von ZDH-ZERT offer their services together under the name of mdc medical device certification GmbH – ein Unternehmen von ZDH-ZERT. ZDH-ZERT e. V. has been founded in 1994 as registrar for ISO 9001/2/3. In 1995 the Notified Body Zertifizierungsstelle Medizinprodukte von ZDH-ZERT e. V., which got the identification number 0538 under the MDD, has been founded. In the past ZDH-ZERT concentrated mainly on the certification small and middle-sized companies, especially in the field of health services and surgical instruments.

mdc's accreditation scope contains medical devices according to MDD 93/42/EEC and in vitro diagnostic devices according to IVDD 98/79/EG. This means that mdc is one of the few Notified Bodies in Germany which can offer the manufacturers of medical devices and in vitro diagnostic devices the necessary certifications for the European market.

mdc's success is based on synergy and co-operation. A worldwide network of representatives, co-operation partners, and most of all a high number of lead auditors and technical experts with preclinical, clinical, technical and management background in medical devices warrant the effective, high level service our clients can rely on.

mdc shares resources with other Notified Bodies and ISO 9000 registrars and contributes actively to the exchange of experience and information on a national and international basis. Moreover mdc's experts serve in international and European standards committees and working groups of the EU Commission.

The Governing Board defining mdc's certification policy within the legal framework represents manufacturers, health professionals and test laboratories and certification bodies.

We are proud that within a short time the marking **CE 0483** on medical devices – indicating our involvement as Notified Body – has contributed to the international reputation of our clients and their products.

In the meantime, due to the competent performance we offer, mdc belongs to the group of Notified Bodies that have achieved a globally known name together with a high reputation. Here mdc enjoys the flexibility of a private company that is necessary to react to the needs of our customers.

mdc understands its task as a Notified Body to serve the public health as well as the medical device industry.

FURTHER INFORMATION AND DOCUMENTS

Requests about device classification, questionnaires, documents to be submitted, time estimates, and/or alternative routes and costs of certification as well as comments on this brochure may be addressed to:

mdc medical device certification GmbH
Kriegerstrasse 6
70191 Stuttgart/Germany

phone: +49-711-253597-0
fax: +49-711-253597-10
e-mail: mdc@mdc-ce.de
web site: <http://www.mdc-ce.de>

On our homepage further information with respect to the field of CE-marking and the certification of quality systems can be found. Under "Downloads", a questionnaire for the preparation of a quotation is available.

Directives, Guidelines and information with respect to standards are available through the following websites:

www.newapproach.org:

Text of EC directives, links to the relevant sectors at the EC Commission, lists of the respective harmonized standards, and status of standardization projects at CEN.

www.europa.eu.int/comm/enterprise/medical_devices/index.htm:

Sector medical devices of the EC Commission with directives, guidelines (MEDDEV documents) and further interesting information

www.dimdi.de:

German texts of law (medical device law and decrees), forms, addresses of authorities and Notified Bodies

www.bfarm.de:

Information about vigilance system and risks

www.zlg.de:

Information about accreditation of notified bodies, quality management registrars and testing laboratories in the field of medical devices in Germany as well as national decisions regarding the activities of Notified Bodies

www.team-nb.org:

Notified Bodies Recommendations (guidelines of Notified Bodies)