

# **Basic Information about the European Directive 98/79/EC on In vitro Diagnostic 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 In vitro Diagnostic Device Directive 98/79/EC (IVDD). Its purpose is to help in vitro diagnostic device manufacturers to understand and comply with the IVDD 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

© mdc medial device certification GmbH

## CONTENTS

<b>CE-MARKING: THE PRINCIPLES OF EUROPEAN DIRECTIVES .....</b>	<b>4</b>
<b>NOTIFIED BODIES.....</b>	<b>5</b>
<b>IVDD: THE IN VITRO DIAGNOSTIC DIRECTIVE 98/79/EC - INTRODUCTION .....</b>	<b>6</b>
<b>CATEGORIZATION OF IN VITRO DIAGNOSTIC DEVICES .....</b>	<b>8</b>
<b>QUALITY SYSTEMS: ISO 9000 - ISO 13485 – CE-MARK.....</b>	<b>9</b>
<b>TECHNICAL FILES - HARMONIZED STANDARDS - CTS .....</b>	<b>10</b>
<b>THE EUROPEAN MEDICAL DEVICE VIGILANCE SYSTEM.....</b>	<b>12</b>
<b>HOW TO OBTAIN THE CE-MARK – STEPS IN THE CERTIFICATION PROCEDURE.....</b>	<b>13</b>
<b>SPECIFIC MDC-CERTIFICATION PROCESS .....</b>	<b>17</b>
<b>MDC – NOTIFIED BODY 0483 .....</b>	<b>19</b>
<b>FURTHER INFORMATION AND DOCUMENTS .....</b>	<b>20</b>

### 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 In vitro Diagnostic Devices Directive 98/79/EC 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 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.

### IVDD: THE IN VITRO DIAGNOSTIC DIRECTIVE 98/79/EC - 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 (IVDD) - 98/79/EC.

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

Under the IVDD an 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

'Specimen receptacles' are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

'Products for general laboratory use' are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

An 'accessory' means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose. For the purposes of this definition, invasive sampling devices or those, which are directly applied to the human body for the purpose of obtaining a specimen' within the meaning of Directive 93/42/EEC shall not be considered to be accessories to in vitro diagnostic medical devices

'Manufacturer' 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. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name.

All in vitro diagnostic devices must meet the applicable 'essential requirements' on safety, performance and labeling as outlined in Annex I of the IVDD. 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 IVDD there are no provisions for a 'grandfathering' approach.

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

For in vitro diagnostics there is no 'classification' as according to the Directive 93/42/EEC. However, there is a categorization as follows:

- Devices according to Annex II, List A
- Devices according to Annex II, List B
- Devices for self testing
- Devices for performance evaluation
- All other in-vitro diagnostics

Depending on the category the manufacturer has to carry out a suitable conformity assessment, as stipulated in Article 9 of the IVDD, according to the relevant Annexes III, IV, V, VI or VII.

Regardless of the category 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 devices.

In principle for all devices there must be a performance evaluation. The manufacturer must present valid data demonstrating performance based on a reference system (as far as possibly available). The submitted data shall provide information as to reference processes, reference materials, known reference values, specificity and measurement units. This data shall originate from experiments in a clinical or suitable equivalent environment or alternatively from relevant literature.

Particulars concerning the performance evaluation can be found in the European standard EN 13612 (presently a draft) and the Common Technical Specifications (CTS) that are addressed in a later chapter.

IVDD, Article 10 rules that, manufacturers who place devices on the market shall notify the competent authorities. Where a manufacturer without a registered place of business in a Member State of the EU places devices on the EU market, he shall designate an authorized representative who is established in the Community.

As from the 8th of December 2003 no in-vitro diagnostic device covered by the IVDD, shall be placed on the market, which do not bear a CE mark. 'Placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for performance evaluation with a view to 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', which will end at 07 December 2005. '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 'devices for performance evaluation' where the manufacturer must keep documentation in accordance with IVDD Annex VIII. The IVDD does not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity.

### CATEGORIZATION OF IN VITRO DIAGNOSTIC DEVICES

The in vitro diagnostics are categorized as follows:

- Devices according to Annex II, List A:

Reagents and reagent products, including related calibrators and control materials, for:

- determining the following blood groups: **ABO system, rhesus (C, c, D, E, e) anti-Kell**
- detection, confirmation and quantification in human specimens of markers of **HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.**

- Devices according to Annex II, List B:

- Reagents and reagent products, including related calibrators and control materials, for:

- determining the **blood groups anti-Duffy and anti-Kidd,**
- determining **irregular anti-erythrocytic antibodies,**
- detection and quantification of the infections **rubella and toxoplasmosis**
- determining the infections **cytomegalovirus and chlamydia**  
diagnosing **phenylketonuria,**
- determining the **HLA tissue groups: DR, A, B,**
- determining the **tumor marker PSA,**

- Reagents and reagent products, including related calibrators, control materials and software for evaluating the risk of **trisomy 21,**

- Devices for self-diagnosis including related calibrators, control materials measurement of **blood sugar.**

- Devices for self-testing:

All devices intended by the manufacturer to be able to be used by a **lay user in a home environment.**

- Devices for **performance evaluation**

All devices intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises.

- All **other in vitro diagnostic devices.**

### 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 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. EN ISO 13485 under consideration of ISO/TR 14969 are another possibility. But harmonized standards are not the only way to demonstrate compliance with the IVDD (see next chapter).

The IVDD 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 IVDD. 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 and under consideration of ISO/TR 14969, does not fully cover the requirements of the IVDD.

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 IVDD
- information about common technical specifications, 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 MDD, 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 - HARMONIZED STANDARDS - CTS

No matter whether the device is for performance evaluation, a device for self-testing, a product according to Annex II (List A or B) or another in-vitro diagnostic device in the sense of the IVDD technical documentation (device master file, technical file, design dossier) is always required. Particular requirements are given in Annex III for all of the devices except the devices for performance evaluation, which are covered by Annex VIII.

The recommended minimum content of a technical file according to Annex III 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 information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the devices, methods of manufacturing and, in case of instruments, design drawings, diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the above mentioned characteristics, drawings and diagrams and the operation of the product,
- in the case of devices containing tissues of human origin or substances derived from such tissue, information on the origin of such material and on the conditions in which it was collected,
- results of risk analysis,
- listing of the applied or partially applied harmonized standards,
- statement regarding compliance with the Common Technical Specifications (CTS),
- evidence that the essential requirements, Annex I, have been met,
- in the case of sterile products or products with a special microbiological state or state of cleanness, a description of the procedures used,
- the results of the design calculations and of the inspections carried out, etc.,
- evidence of the compatibility with other products
- test reports
- adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (if available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used; such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references,
- label and instructions for use,
- the results of stability studies,
- documentation concerning the quality assurance system (or references to such)

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 documentations directly to the Notified Body.

The IVDD 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 use 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 Communities. 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 (IVDD, Article 5). Harmonized standards are still voluntary. Where the manufacturer does not apply a harmonized standard he has to document the solutions adopted to meet the essential requirements of the directive.

A new aspect in the field of medical devices are the Common Technical Specifications (CTS). By compliance with these rules the essential requirements (IVDD, Article 5) as far as they are covered by the CTS are considered to be fulfilled. By non-compliance with the CTS, if for duly justified reasons, manufacturers must adopt solutions of a level at least equivalent thereto. CTS are drawn up for the devices in List A of Annex II and, where necessary, the devices in List B of Annex II. In these specifications appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials are established. The CTS are elaborated under the responsibility of the European Commission and published in the Official Journal of the European Community.

### THE EUROPEAN MEDICAL DEVICE VIGILANCE SYSTEM

Article 11 of the IVDD requires Member States, in relation to CE-marked in-vitro diagnostic devices, to take the necessary steps to ensure that any information brought to their knowledge about

- any malfunction, failure 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, directly or indirectly, might lead to or have led to the death of a patient, or user or of other person or to a serious deterioration in their 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

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

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 III, IV, VI, and VII. 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 far as possible, the concerned parties. If the measures of the Member State are justified the Commission will remit the necessary measures for the EC. Like that, a Member State has the right by the protection clause in article 8 of IVDD, also in case of products being correctly CE-marked, to intervene immediately, if it consists acute danger for the health of patients, user or others.

### 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.

IVD manufacturers, who have no devices listed in Annex II, no devices for self-testing and no devices for performance evaluation, 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.

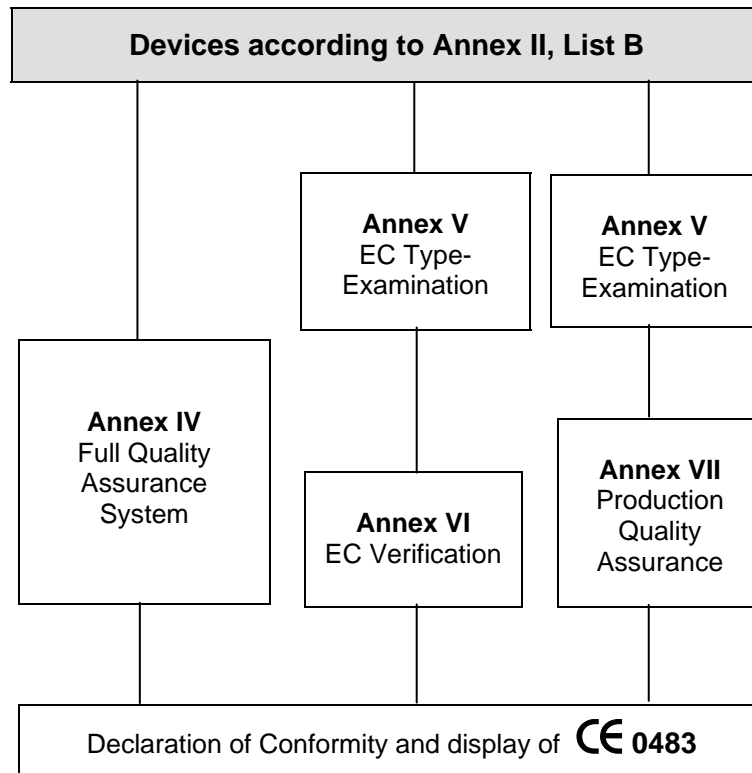
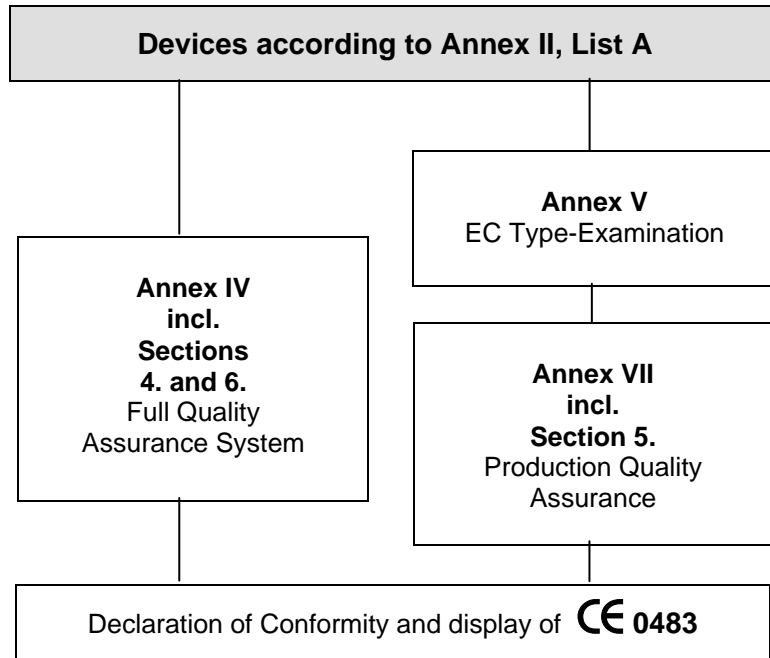
Devices according to Annex II and devices for self-testing require the certification by a Notified Body before the manufacturer can put the CE mark in combination with the number of the Notified Body on the device. Depending on the listing of the in vitro diagnostic device, the manufacturer has the choice between different certification routes as graphically shown on the following pages.

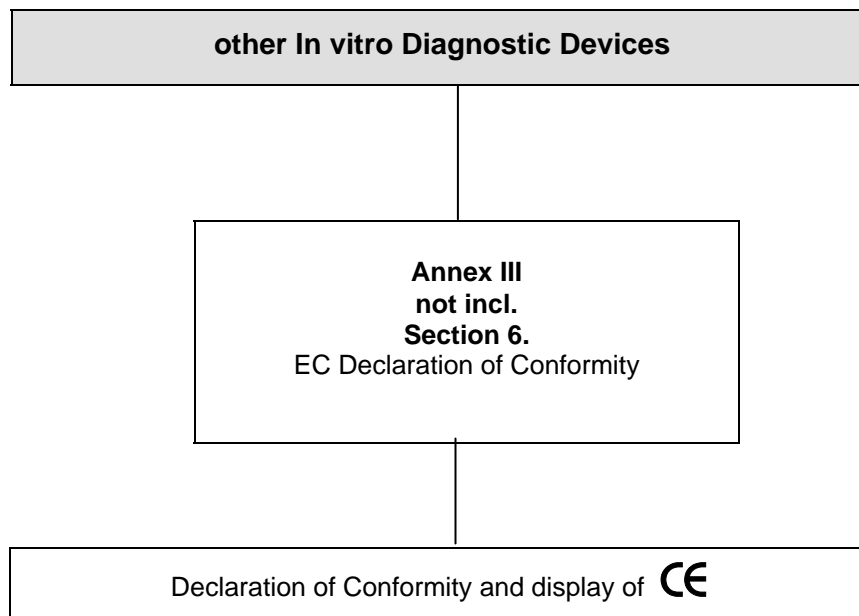
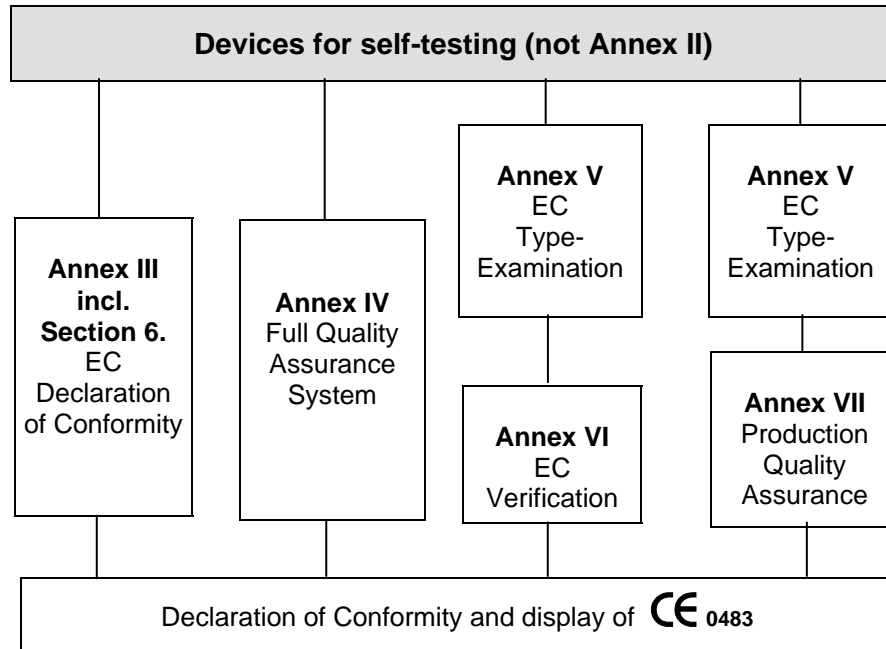
The certification usually includes the following steps:

- decision whether or not a product is an in-vitro diagnostic medical device in the sense of the IVDD
- categorization 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 categorization by the Notified Body, time and cost estimation for different certification routes; discussion and choice of the most suitable certification route by the manufacturer
- formal application and certification contract
- submission of documents to the Notified Body
- evaluation of the submitted documents and report
- if required performance of product testing
- 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
- in case of Annex II list A devices evaluation of the manufactured device batches by the Notified Body
- surveillance audits (usually one audit per year)
- full re-audit and issuing of a new certificate after five years

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

**II. CONFORMITY ASSESSMENT PROCEDURES – (ANNEXES II TO VII)**





### **Annexes III – VII of the In vitro Diagnostic Device Directive 98/79/EC (IVDD)**

#### **ANNEX III - EC DECLARATION OF CONFORMITY:**

A conformity assessment procedure in which the manufacturer himself declares the compliance of his devices with the IVDD. This is required for all in vitro diagnostic devices, except those listed in Annex II or devices for performance evaluation. For devices for self-testing the manufacturer has to lodge in addition an application for examination of the design, according to section 6, with a Notified body.

The examination of the design is a complete assessment of the technical file for compliance with the essential requirements according to Annex I.

#### **ANNEX IV - FULL QUALITY ASSURANCE SYSTEM:**

Most comprehensive conformity assessment procedure for the aspect of quality systems. A full quality assurance system has to include all steps from the product development right through to the end control. The manufacturer may choose the harmonized standards EN ISO 13485:2003 in combination with the respective guidance standard ISO/TR 14969 as the basis of his quality system or use an equivalent quality system suitable to fulfill the requirements of the IVDD. This procedure is applicable for all products according to Annex II and may be implemented for devices for self-testing. Section 4 describes the examination of the design of the product, which applies to Annex II List A devices. This Section is similar to Annex V - EC Type-Examination with the difference, that in-house test results obtained by the manufacturer under his full quality management system can be acknowledged by the Notified body. For the devices according to Annex II List A verification of the manufactured products (batch release) by a Notified body, according to section 6, is necessary.

#### **ANNEX V - EC TYPE-EXAMINATION:**

A conformity assessment procedure for the product design which involves examination and testing of representative samples of the device by a Notified Body and certification that the device meets the applicable essential requirements. Manufacturer supplied test reports should originate from a third party and fulfill certain criteria. Testing by the manufacturer is possible under supervision of the Notified body. EC type-examination may be applicable to List A devices and devices for self-testing. In each case Annex V is only allowable in combination with either Annex VI or Annex VII.

#### **ANNEX VI - EC VERIFICATION:**

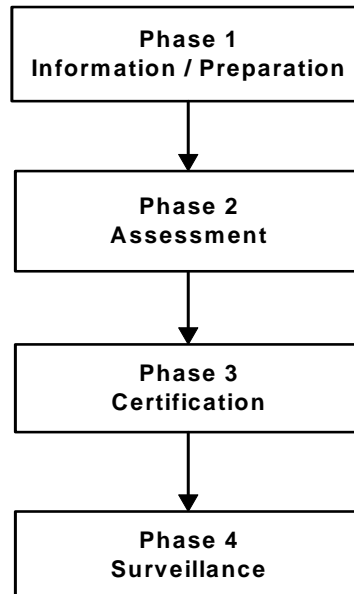
A conformity assessment procedure in which the Notified Body examines and tests every individual device or devices taken on a statistical basis, if the manufacturer manufactures homogeneous batches. The Notified Body releases individual devices or batches. EC Verification may be applied to Annex II List B devices and for devices for self-testing in combination with an EC type examination.

#### **ANNEX VII - PRODUCTION QUALITY ASSURANCE:**

This conformity assessment process refers to a quality system which has to include all steps (with the exception of the design phase) from the raw material supply right through to the end control. Application of the quality system must ensure that the devices conform to the type described in the EC type-examination certificate. The manufacturer may choose the harmonized standard standards EN ISO 13485:2003 in combination with the respective guidance standard ISO/TR 14969 as the basis of his quality system. Annex VII, in combination with Annex V, may be followed for all Annex II IVDs and devices for self-testing. For Annex II List A products verification of the manufactured products (batch release) by a Notified body, according to section 5, is necessary.

### 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 or 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 and/or qualified subcontracted laboratories to perform necessary product tests to the applicant. The documentation is assessed by the proposed auditors and/or experts. In procedures, which may include product tests, the tests are performed and their results are assessed. 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 is issued. In case of a rejection mdc informs the applicant about the conditions for getting the certificate. The validity of certificates according to the IVDD 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, the manufacturing processes or the 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 or ISO 13485. These certifications can be realized by mdc or together with accredited cooperation 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/EEG 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](mailto: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](http://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](http://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](http://www.dimdi.de):

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

[www.bfarm.de](http://www.bfarm.de):

Information about vigilance system and risks

[www.zlg.de](http://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

<http://www.team-nb.org>:

Notified Bodies Recommendations (guidelines of Notified Bodies)