



TÜV NORD CERT GmbH

Information folder:

CE Marking and Conformity Assessment Procedures for
Medical Devices

Medical Devices

93/42/EEC

Active Implantable Devices

90/385/EEC

TÜV NORD CERT GmbH, Certification Body for Medical Devices

Explanations of Conformity Assessment Procedures

THE ROUTE TO THE CE MARK

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Introduction

93 / 42 / E E C

Since 01.01.95 all medical devices have been subject to the "Medical Devices Directive" 93/42/EEC.

This directive specifies that all medical devices must be provided with the CE mark as from 14.06.98. The medical devices are divided into four classes.

Depending on the risk potential for the patient, user or third parties, different so-called "conformity assessment procedures" have to be carried out. In many cases it is necessary to call upon the services of a "Notified Body".

90 / 385 / E E C

The directive regarding active implantable medical devices, 90/385/EEC, entered into force on 20.06.1990.

TÜV NORD CERT GmbH is registered under number



as "notified body" for medical devices and active implantable medical devices, among others.

Performance of conformity assessment procedures in accordance with Medical Devices Directive 93/42/EEC and the Directive for Active Implantable Medical Devices 90/385/EEC is explained in the following chapters of this information folder.

As the procedures are very different in some respects, we have included descriptions of the four different procedures in this folder.

- **Certification of QM systems**
to Directive 93/42/EEC Annex II without Section 4 / Annex V / Annex VI,
to Directive 90/385/EEC Annex 2 without Section 4 / Annex 5
- **EC type examination**
to Directive 93/42/EEC Annex III,
to Directive 90/385/EEC Annex 3
- **EC verification**
to Directive 93/42/EEC Annex IV,
to Directive 90/385/EEC Annex 4
- **EC design examination**
to Directive 93/42/EEC Annex II, Section 4,
to Directive 90/385/EEC Annex 2, Section 4

The following forms, which are necessary for the procedure, are attached. Please complete these, sign them and return to us as soon as possible.

Application for performance of the conformity assessment procedure, consisting of the following individual forms:

A Application

B Information regarding the manufacturer, his representative and subcontractors

C Information on the products

D Information on the quality system

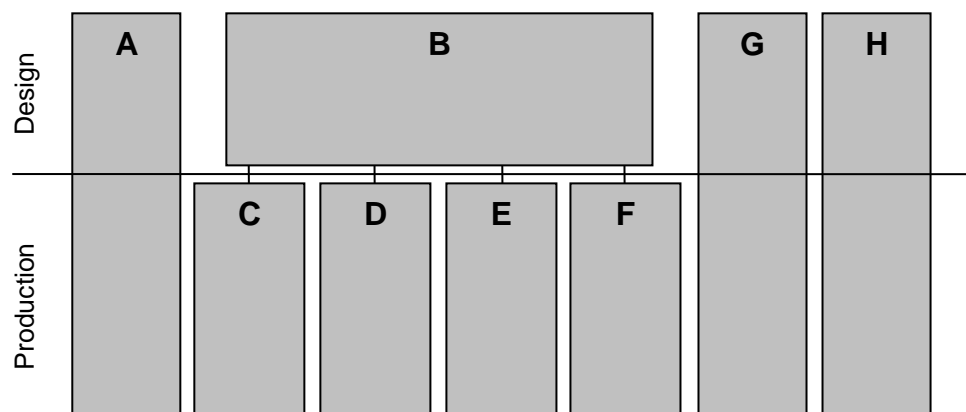
All the forms are, naturally, also available on electronic data carriers.

The modular system

Explanations

The "modular system" can be compared to a set of building blocks from which the EC Commission selects those processes for the different EC Directives which are suitable for proving conformity with the "basic requirements".

This modular system was made known as a basic concept in EC Directive 90/683/EEC and is used for all directives based on the "new approach", which among others include the Machinery Directive, the Directive concerning Personal Protective Equipment and also the Directive concerning Active Implantable Medical Devices and the Medical Devices Directive.



MODULES

The modules are each identified with a letter from A-H. Each letter corresponds to a certain conformity assessment procedure.

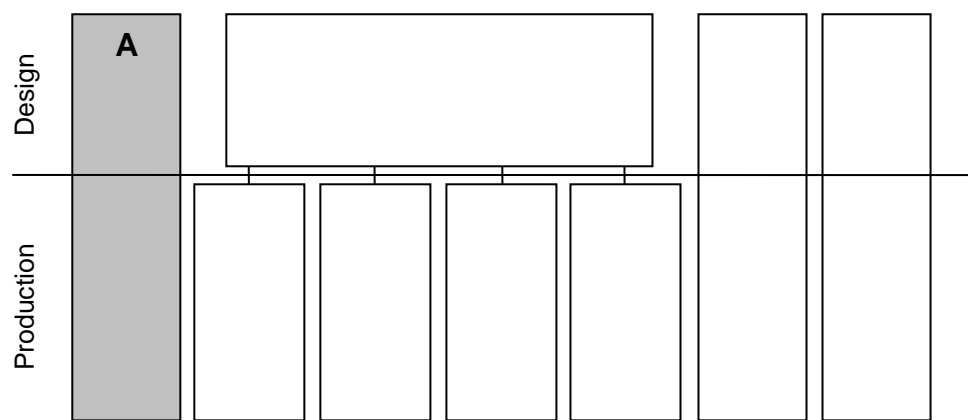
- A Manufacturer's Declaration of Conformity
- B EC type examination
- C Conformity to type
- D Production quality assurance
- E Product quality assurance
- F EC verification
- G EC unit verification
- H Full quality assurance

Some EC directives only use a small selection of the available modules, others - like the Medical Devices Directive - only allow certain modules for certain classes of products.

The Medical Devices Directive applies for approximately 400,000 different products with various different risks for patients, users and third parties. Therefore medical devices are divided into four product classes I, IIa, IIb and III, depending on their risk potential. Class 1 applies for devices with the lowest and Class III for devices with the highest risk potential.

The following conformity assessment procedures apply for the different classes.

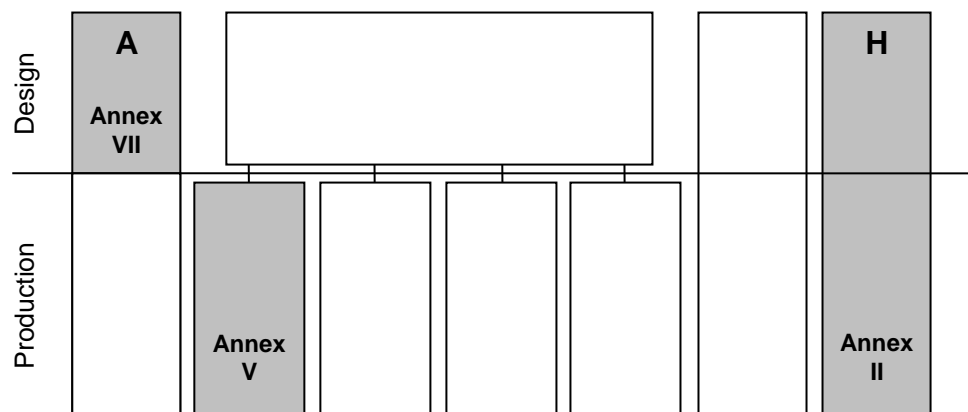
CLASS I



In the case of Class I devices, the manufacturer provides the declaration of conformity according to Annex VII of the directive and applies the CE mark to the products on his own responsibility. It is not necessary to involve a Notified Body for these products.

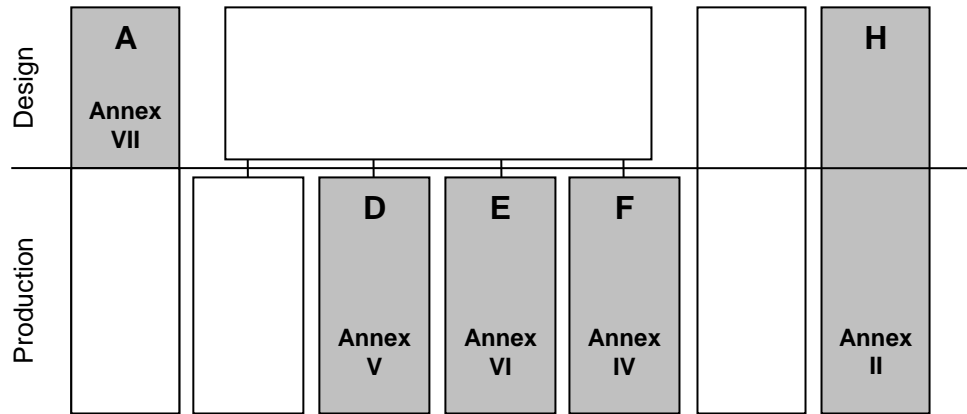
**CLASS I
STERILE**

If Class I devices are placed on the market in sterile condition, in addition to the manufacturer's declaration of conformity, the aspect of sterilisation must be covered by means of a conformity assessment procedure according to Annex V or Annex II without Section 4.



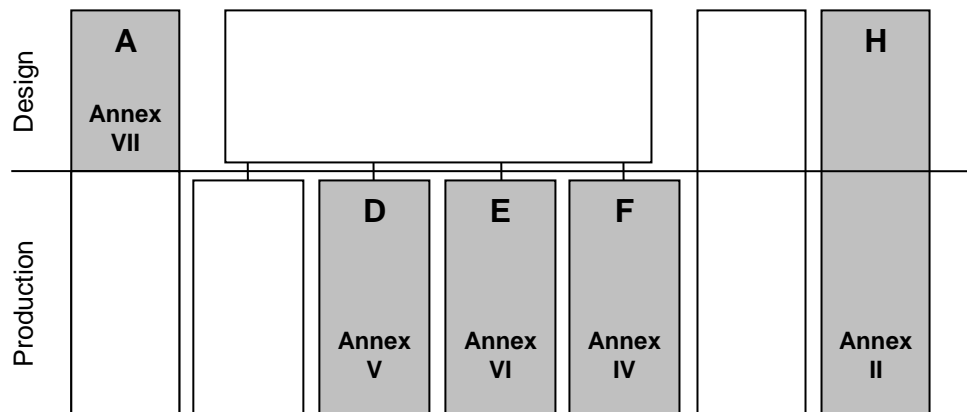
**CLASS 1
MEASURING
FUNCTION**

For Class I devices with a measuring function, in addition to the manufacturer's declaration of conformity, one of the procedures according to Annexes IV, V or VI must be audited by the Notified Body for the aspect of the measuring function. As an alternative, a conformity assessment procedure according to Annex II without Section 4 is possible.



CLASS IIa

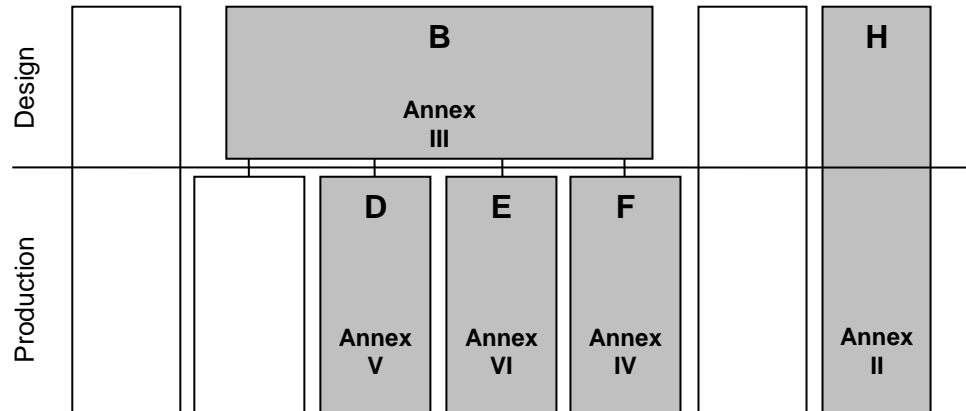
The following conformity assessment procedures are possible for Class IIa devices:



In addition to the combination of the procedure according to Annex VII with a procedure according to Annexes IV, V or VI, the procedure according to Annex II without Section 4 is possible. This comprises the certification of a "full quality assurance system" (from development through production up to placing on the market).

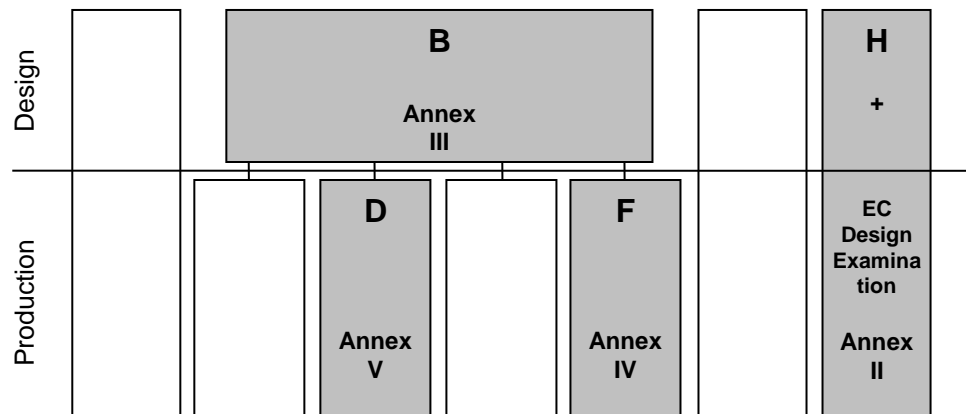
CLASS IIb

In the case of Class IIb devices, the manufacturer's declaration of conformity is replaced by an EC Type Examination according to Annex III (see Chapter 4).



CLASS III

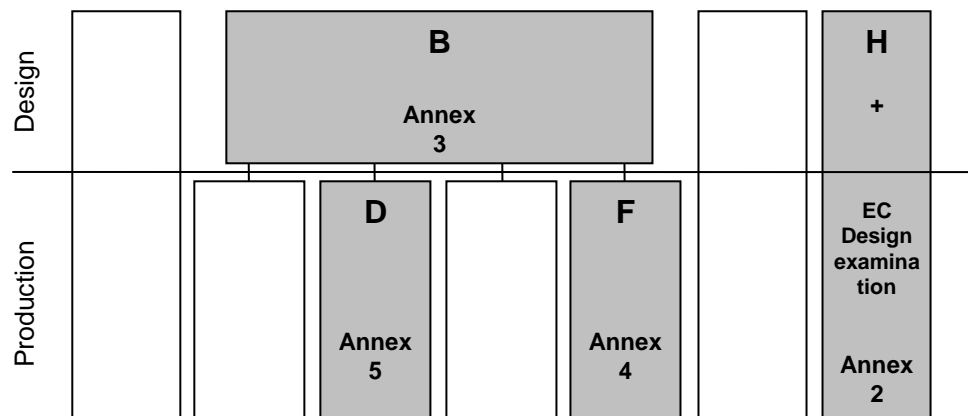
For Class III devices, in addition to certification of the "full quality assurance system" for each product, the EC design examination must be carried out by the Notified Body (see Chapter 3).



As an alternative, the procedure of EC type examination can be carried out in conjunction with the EC verification procedure according to Annex IV or the EC declaration procedure for compliance with the Type in accordance with Annex V (production quality assurance).

For active implantable medical devices, the manufacture can either perform the procedure of EC Declaration of Conformity according to Annex 2 without Section 4 (full quality assurance system) or the procedure of EC Type Examination in accordance with annex 3 in conjunction with the procedure of EC Verification in accordance with Annex 4 or the procedure of EC Declaration for compliance with the Type according to Annex 5 (production quality assurance.

In addition to the certification of the "Full quality assurance system", an EC design examination according to Annex 2, Section 4 has to be carried out by the Notified Body (see Chapter 3).



Certification of QM systems and conformity assessment procedures for medical devices

Description of the certification procedure of quality management / quality assurance systems for medical devices.

Description of the conformity assessment procedure according to Medical Devices Directive 93/42/EEC (MDD)

Annex II without Section 4, Annex V, Annex VI

and

according to the Directive concerning Active Implantable Medical Devices 90/385/EEC (AIMDD)

Annex 2 without Section 4, Annex 5

Basis for quality assurance systems

In the case of certification procedures for quality assurance systems according to one of Annexes II, V or VI of the Medical Devices Directive as well as Annex 2 or 5 of the Directive for Active Implantable Medical Devices, the requirements of international standard EN ISO 13485 "Medical Devices - Quality Management Systems - Requirements for regulatory purposes". This standard is harmonized as an independent standard with EU directives 93/42/EEC, 98/79/EC and 90/385/EEC.

Before a certification or a conformity assessment procedure can be initiated, it must be applied for from the Certification Body. For this, the client receives the "Printed Form Set A-D" as well as contracts which state the obligations of both client and supplier and the legal conditions for the performance of the certification, issue of the certificate and surveillance and monitoring.

In the forms, the client gives exact information about his company, the activities and services undertaken in connection with medical devices, the products, their purpose and if appropriate, any special features (e.g. sterile, components of animal origin), the selected conformity assessment procedure and the desired scope of the certificates. If the production or parts of production are subcontracted (e.g. sterilisation, cleaning, assembly, testing), precise information must be given with regard to the subcontractors or OEM manufacturers as well as proofs of certification of the QM system of the subcontractor according to EN ISO 13485, or certificates regarding conformity assessment procedures.

In addition, the company management of the client names a contact person who is responsible for organisation and performance of the certification. This is generally the Quality Management Representative.

The completed forms and contracts as well as any other documents submitted by the applicant are sent to the certification body and serve to check the scope of the conformity assessment procedure and to establish if the basic prerequisites for a certification procedure are present.

Following a successful contract review, the certification body initiates the certification or the conformity assessment procedure and plans the necessary steps and resources in cooperation with the client.

Certification of QM systems is performed by means of a two-stage audit procedure, and in the case of conformity assessment procedures, additionally through review of the technical documentation of the products.

PRELIMINARY
AUDIT

Independently of the order for a complete certification procedure, it is possible to perform a so-called "preliminary audit". The preliminary audit is an additional service which does not have to be used in every case. The preliminary audit is divided into the following steps:

- Review of QM documents submitted by the client (QM Manual, documented procedures and work instructions if relevant)
- Performance of an audit on site
- Writing of a short report

The aim of the preliminary audit is to identify weaknesses in the QM system for the customer - in particular with regard to the documentation and in the implementation of the QM system (interaction of processes, determination of responsibilities and authorities). The result of the preliminary audit is documented in a short report, which contains the main findings and an evaluation of these. The scope of the audit is laid down in cooperation with the client, and the audit is generally performed by an auditor (lead auditor).

**INITIAL
CERTIFICATION**

Initial certification of a QM system is carried out in two audit stages. The Stage 1 audit serves to establish the readiness for certification of the company and takes place in part or completely at the client's premises. The Stage 2 audit serves to assess the implementation and effectiveness of the management system. It normally takes place completely at the client's premises; in some cases parts of the audit may take place at the subcontractor's premises.

STAGE 1 AUDIT

The Stage 1 audit comprises evaluation of:

- the QM documentation of the company
- the location-specific prerequisites and the readiness for certification of the personnel
- the known, described and implemented targets, key services and performances, core processes
- the scope of the QM system (and the subsequent certificate) and consideration of the legal and official aspects
- the resources and focus points for the Stage 2 audit and
- the internal audit and the management review.

A large part of the basic QM documentation must be submitted to the certification body at least 4 weeks before the Stage 1 audit. The documentation must be submitted in German or English. The basic documentation includes, among other things:

- the quality management manual
- the quality policy of the company
- the current organisation chart of the company
- a list of all controlled documents of internal origin on which the quality management system is based (e.g. documented procedures, work instructions, SOPs, manufacturing instructions, test instructions, printable forms)
- a list of all documents of external origin on which the quality management system is based (e.g. directives, laws, standards)
- the documented procedures required by EN ISO 13485 and the EU directives that apply to medical devices (MDD, AIMDD)
- further documents containing other additional rules regarding the aforementioned documented procedures
- a list of all medical devices (models, variants) which are put into circulation by the client

The documents submitted must be legible and easy to read, current and clearly identifiable (e.g. company name, company logo, title, document number, revision status/issue, page numbers, signature).

The auditor documents the audit findings (set-actual comparison) and the result of the Stage 1 audit in a report. If nonconformities are identified, the company must send the audit additional documents for evaluation prior to the Stage 2 audit.

When the certification body has all the information regarding the Stage 1 audit, it decides if the Stage 2 audit can be carried out.

In cases where a conformity assessment procedure has been applied for by the client, the technical documentation and/or design dossier must also be submitted to the notified body for all products/product groups applied for at least 4 weeks before the Stage 1 audit. These documents must also be legible, easy to read, current and clearly identifiable. The guidelines of the "Global Harmonization Task Force" (GHTF) and the recommendations of the "Co-ordination of Notified Bodies Medical Devices"

(NB-MED) may provide help with content and structure of the technical documentation to be submitted. (see also Chapter 7 "Useful links on the Internet").

The evaluation of the technical documentation and/or design dossier serves to establish if a product fulfils the "basic requirements" of the relevant EC Directive and if the solutions selected by the manufacturer are plausible and sufficient, and if they correspond to the current state of technology.

Main points of emphasis of the evaluation are, for example:

- selected solutions for fulfilment of the basic requirements (e.g. applied standards)
- Design and development documentation (design dossiers)
- Proofs regarding product safety (e.g. biological compatibility, sterilisation validation, electrical safety)
- Clinical evaluation, clinical studies, proofs of effectiveness
- Records regarding risk management
- Packaging and product stability
- Accompanying materials (identification, instructions for use)

STAGE 2 AUDIT

When all the information regarding the Stage 1 audit is available, the certification body decides if the Stage 2 audit can be carried out.

During the Stage 2 audit, the effectiveness of the QM system that has been established is examined by means of random sampling. The basis of this examination is the Medical Devices Directive 93/42/EEC and/or the Directive concerning Active Implantable Medical Devices 90/385/EEC. The audit questionnaires are used as a basis for the audit.

The task of the company during the audit is to demonstrate that its documented procedures are implemented in practice and that they conform with the requirements of regulations and standards and of the relevant directives. Following the end of the audit, the client is informed of the result in a final meeting. The result is documented in a report.

**ISSUE OF
CERTIFICATE**

The certificate is issued following positive review of the certification procedure by the Head of the Certification Body. If the contract regarding the certification has been signed and returned, the certificates are sent to the client together with the contract

and the audit report. The period of validity of the certificate is three or five years. Annual surveillance audits must be carried out.

SURVEILLANCE

The QM elements Responsibility of the Management, Quality Management System, Corrective and Preventive Actions and Internal Quality Audits are assessed in every surveillance audit. The further elements are distributed between two surveillance audits. The date for the audit is agreed with the client.

In addition, items of technical documentation are evaluated on a random sample basis during surveillance audits.

The size of the random samples and also the selection of the items of technical documentation are based on the number of products, the technologies used and the risk potential (Class) of the products.

RECERTIFICATION

A repeat audit for extension or new issue of the certificate (recertification) for a further three or five years must be conducted in the company before expiry of the certificates. In the repeat audit, the effectiveness of the entire QM system is checked on a random sample basis. Any changes to the QM system must be submitted in writing by the client in advance, along with the corresponding documents. The audit is carried out as described in Phase 3 of this description. The selection of the technical documentation to be assessed takes the previous assessments and also the current state of technology into account.

CHANGES

All major changes that are planned to the QM system and/or the product range must be communicated to the "Notified Body".

If further products are taken up into the scope of certification following the initial certification procedure, the applicant submits Form C - "Product". The certification body specifies all the further necessary measures. The measures may include:

- Request for further documentation
- Initiation of a supplementary audit
- Requirement for further inspections.

The extension of the certification scope follows positive evaluation of the documentation by the Head of the Certification Body. The client then receives a modified / extended certificate.

Conformity assessment procedures

Description of the certification
procedure

EC design examination
according to Medical Devices Directive
93/42/EEC

Annex II, Section 4

and

according to the Directive concerning
Active Implantable Devices
90/385/EEC

Annex 2, Section 4

Information on EC design examination

The EC design examination consists of a pure documentation examination. This procedure can only be used for Class II medical devices or active implantable devices.

Within the framework of this documentation examination all aspects of a product are considered with regard to its:

- Safety
- Function
- Compatibility
- Clinical effectiveness

The aim of the examination is to prove complete compliance of the product with the basic requirements described in the respective Annex I of the Medical Device Directive / Directive concerning Active Implantable Medical Devices.

EVALUATION

For this purpose, the documentation compiled by the manufacturer is evaluated by experts from the Notified Body.

This evaluation can be compared with a Type Examination, but in the design examination it is not the product itself but the entire development documentation that is evaluated.

From this evaluation result the particular requirements as regards the structure and the components of the technical documentation. With the help of the documentation the client must prove the compliance of the product with the basic requirements of the Medical Devices Directive / Directive concerning Active Implantable Medical Devices.

In the course of the evaluation the experts follow the aspects described in the respective Annex with regard to:

- Chemical, physical and biological effect
- Infection and microbiological contamination
- Design aspects
- Measuring function
- Protection against ionising radiation
- External or internal energy sources
- Information from the manufacturer.

Generally, the evaluation is carried out based on the existing product standards. If no product-specific standards exist, aspects of other standards are used for the evaluation. Here, first the so-called "harmonized standards" are taken into consideration. If these have not yet been officially issued, international or national standards are used.

The result of the evaluation is summarised in a test report.

RE-EVALUATION

In case of a negative result, the documentation has to be corrected or augmented. The products themselves may possibly have to be corrected or additional tests have to be demonstrated and proven.

The augmented and/or additional documentation is evaluated afresh.

CERTIFICATE

If the evaluation result is positive, the EC design examination certificate is issued. This certificate is valid for 5 years.

The EC design examination certificate alone, however, does not entitle the manufacturer to display the CE mark on his products.

In addition, a conformity assessment procedure must be carried out in accordance with Annex II without Section 4 (Medical Devices Directive), or Annex 2 without Section 4 (Directive concerning Active Implantable Medical Devices).

Conformity assessment procedures

Description of the certification
procedure

EC type examination

according to Medical Devices Directive
93/42/EEC

Annex III

and

according to the Directive concerning
Active Implantable Devices

90/385/EEC

Annex 3

Information regarding the EC Type Examination

The EC type examination is a product assessment. This procedure can only be used for medical devices of Class IIb or III or for active implantable medical devices. Within the framework of this product assessment, all aspects of the product are examined with regard to the:

- Safety
- Function
- Compatibility

The aim of the examination is to prove complete compliance of the product with the basic requirements described in the respective Annex I of the Medical Devices Directive / Directive concerning Active Implantable Medical Devices.

EXAMINATION

Generally, the necessary examination is carried out based on the existing product standards. If no product-specific standards exist, aspects of other standards are used for the examination. Here, first the so-called "harmonized standards" are taken into consideration. If these have not yet been officially issued, international or national standards are used.

If no standards exist, the Notified Body creates a test programme with whose help the basic requirements are covered. The test programme is already presented to the client during the offer phase.

The necessary tests are performed in the laboratories of the "Notified Body" or in accredited external laboratories.

The result of the tests are summarised in a test report.

RE-EXAMINATION

If the result is negative, the products have to be reworked and presented again for examination and testing.

C E R T I F I C A T E

If the result is positive, the EC Type Examination is issued, which is valid for 5 years.

The EC design examination certificate alone, however, does not entitle the manufacturer to display the CE mark on his products. In addition, a conformity assessment procedure must be carried out in accordance with Annexes IV, V or VI (Medical Devices Directive) or Annex 4 or 5 (Directive concerning Active Implantable Medical Devices).

Conformity assessment procedures

Description of the certification
procedure
EC verification

according to the Medical Devices
Directive
93/42/EEC
Annex IV

and

according to the Directive concerning
Active Implantable Medical Devices
90/385/EEC
Annex 4

Information regarding the EC verification

EC verification according to Annex IV is a product assessment. In this procedure the manufacturer can decide if each individual product or samples of a production batch is tested. Statistical verification is only possible for batches larger than 300 products because of the framework conditions described in the Medical Devices Directive.

STATISTICAL VERIFICATION

A further prerequisite is proof of normal distribution of the aspects to be examined. During the contract review, the "Notified Body" gives information regarding the number of products to be examined and tested.

The number of products to be examined and tested is determined on the basis of Table VII-A of ISO 2859 Part 1. Under certain conditions, the test level can be reduced to a lower level, which means that the number of products to be examined and tested is reduced.

During the examination and testing of the individual product and also the statistical verification, the important aspects are compiled by the "Notified Body" in the form of a test plan. The aspects are selected in such a way that the product characteristics can be examined in particular with regard to:

- Safety
- Function
- Accuracy
- Compatibility

If an EC type examination was performed beforehand, the conformity of the product with the type must also be examined.

APPLICATION

The application for the EC verification must be made afresh for each batch. The examinations are performed either in the laboratories of the "Notified Body" or in accredited external laboratories.

If the result is negative, either the test level has to be raised (only in the case of statistical control) or the products are reworked and presented again for examination and testing.

C E R T I F I C A T E

If the result is positive, the notified body issues a certificate for the tested patch.

Together with the declaration of conformity of the manufacturer according to Annex VII of Class IIa medical devices, the conditions are met for application of the CE mark.

For medical devices of Class IIb or III or for active implantable medical devices, CE marking is possible together with the EC type examination certificate. For products which are put into circulation in sterile state, proof of a conformity assessment procedure according to Annex V is necessary for the sterilisation process.

EC verification procedure is particularly recommended for small companies with a small range of products and for companies with batch runs of more than 10,000. However, it is often also used by companies during the time when a QA system is in the process of being introduced, prior to certification.

Effects of Amending Directive 2007/47/EC

On 21 September 2007, Directive 2007/47/EC for amendment of Directives 93/42/EEC (MDD) concerning medical devices and Directive 90/385/EEC (AIMDD) concerning active implantable medical devices were published. This amending directive had to be transposed into national law by 21.12.2008. The transitional period for manufacturers in order to fulfil the new/amended requirements extended up to 21.03.2010.

The changes concern, for example, the following (list is not exhaustive):

- Further EC directives applicable to the respective product were included (e.g. machinery directive, directive concerning personal protective equipment)
- Clinical data are required for all medical devices (including Class 1)
- Terms and definitions were extended/made more specific (e.g. borderline products, continuous use)
- Some classification rules (Annex IX) were made more specific/extended (e.g. Rules 5, 6, 7, 15 and 16)
- Software is now defined as an active medical device and requirements for software validation were included
- Outsourced processes concerned with development and manufacture must be monitored more closely by the notified bodies
- Class 1 devices (sterile and measuring function) can also be assessed for conformity according to Annex II without Section 4 (full quality assurance system)
- The rules for the authorised representative (for manufacturers from non-EU states) were made more specific

- Instructions for use must contain their date of issue or the date of the last revision
- Rules for specific labelling for phthalate-containing devices, which are now included

Useful links on the Internet

The Internet offers a wide variety of detailed information on the subjects of medical devices, conformity assessment and certification.

The following list contains links where you will find such information on various aspects of medical device legislation and other related matters.

We would like to emphasise at this point that we are not responsible for the contents of the websites listed below.

We try to keep the list of links up-to-date. However, please note that links may change over time and we are not always able to update this list immediately.

Federal Ministry of Health

Includes Medical Devices Act (MPG) and associated ordinances.

www.bmg.bund.de

Federal Institute for Drugs and Medical Devices

Includes information on risks associated with medical devices, recommendations of manufacturers, recommendations of the BfArM)

www.bfarm.de

Central Authority of the Laender for Health Protection with regard to Medicinal Products and Medical Devices (ZLG)

Includes responses and resolutions of the exchange of experience circle of the notified bodies in accordance with the Medical Devices Act (MPG)

www.zlg.de

German Institute of Medical Documentation and Information

Includes laws and ordinances, information for publicizing products (first putting into circulation) and clinical trials, reporting documents for events and incidents, literature databases from the medical area and associated areas

such as pharmaceutical products, toxicology, medical devices, biology and psychology.

www.dimdi.de

Robert Koch Institute

Includes information and guidelines on recycling of medical devices (RKI guidelines)

www.rki.de

German Institute for Standardization

Includes information on the status of standardization, references to national and international standards committees

www.din.de

European Commission - Enterprise and Industry

Medical devices

Includes guidance, medical device directives (MEDDEV), list of the harmonized standards

www.ec.europa.eu/enterprise/sectors/medical-devices

New Approach Notified and Designated Organisations (NANDO)

Includes information of the European Commission regarding accreditation and notified bodies

www.ec.europa.eu/enterprise/newapproach/nando

Notified Body Operations Group (NBOG)

Includes guidelines for notified bodies (also of interest to manufacturers)

www.nbog.eu

European Association of Notified Bodies for Medical Devices (Team-NB)

Includes recommendations for manufacturers and notified bodies

www.team-nb.org

Global Harmonization Task Force (GHTF)

Includes guidelines for manufacturers and notified bodies

www.ghtf.org

About TÜV NORD CERT and contact details

TÜV NORD CERT GmbH has numerous offices and offers its services on a local basis. Our experts are always ready to assist you. We are always pleased to hear from you.

You can reach us as follow:

By Phone: 0511 9986-1222 or Email medical@tuev-nord.de

The current contact data of our international offices can be found on our website at www.tuev-nord.de under the heading "INTERNATIONAL" -> "Presence".