

Council Directive 93/42/EEC from June 14, 1993, on medical devices

Practice-oriented summary of the most important aspects and requirements contained in Directive 93/42/EEC

What exactly is a Medical Device?

Medical devices are: instruments, appliances, apparatus, materials or other articles including software for the following purposes:

Purposes of Medical Devices

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, injuries or handicaps
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

Borderline to Medicines

Main effect is not achieved by pharmacological, immunological or metabolic means.

What can be regarded as an Accessory

Articles that are not medical devices themselves, but are used in conjunction with a medical device – e.g. add-on devices or disposable articles – also come under the scope of this Directive. These objects can be classified separately to the product itself according to Annex IX of the Medical Devices Directive and be treated as a product covered by the Directive.

Devices for Special Purposes

1. Custom-made products, which are

- manufactured by qualified persons
- according to written prescription
- exclusively for named persons.

2. Products for clinical testing.

These products are under the scope of the Directive; however, a CE marking is not required.

Who is the Manufacturer according to the Directive?

The Directive defines the manufacturer as the natural/legal person who is responsible for the design, manufacture, packaging and labeling of a medical device with regard to marketing it in his own name, regardless of whether these actions are performed by that person himself or a third party deputizing for this person.

Manufacturers outside the EU require, in addition, a representative within the EU.

Essential Requirements of the Product

Annex I of the Directive requests that the safety and health of patients, users and, if applicable, other persons, must not be placed in danger during intended use of the product and that any risks associated with the product are justifiable compared to the associated benefits.

In addition to these general requirements there are other requirements, which refer to the construction:

- Chemical, physical and biological properties (toxicity, compatibility...)
- Protection from infection and microbial contamination (processing, packaging)
- Features with regard to construction and the environmental conditions (minimizing of risks)
- Measuring function (accuracy, displays)
- Protection against radiation (intentional or unintentional radiation, ionizing radiation)
- Devices with external or internal energy source (protection against electrical or thermal risks)
- Protection from hazards as a result of administration of energy or substances to patients
- Provision of information by the manufacturer (labeling, instructions for use)
- Establishing clinical data

Classification of Medical Devices by their Hazard Potential

Annex IX of the Directive stipulates the classification of devices – according to the hazard potential – in classes I (low), IIa, IIb, and III (high). Depending on classification of the

product, different conformity assessment procedures apply. The Directive includes 18 classification rules.

Classification Criteria:

- Duration of use:
 - transient (under 60 min.)
 - short term (up to 30 days)
 - long term (more than 30 days)
- Level of invasiveness:
 - non invasive
 - invasive through body orifice
 - surgically invasive
 - implantable
- Location of use:
 - on central circulatory system
 - on central nervous system
 - outside these
- Energy supply:
 - non active
 - active

If you have any queries regarding classification of your product, our specialists will be happy to help.

Layout of Annex Contents

Annex I: Essential Requirements

Annex II: Complete Quality Management System

The manufacturer has a quality management system e.g. EN ISO 13485:2003, fulfills the additional requirements of the Directive (e.g. market surveillance, reporting, document storage, fulfillment of the essential requirements as laid down in Annex I) and declares the conformity of his products with the Directive. In the case of devices in class III a product design review is also stipulated.

Annex III: Type Examination

A Notified Body carries out a type test to the essential requirements of Annex I of the Directive and issues a type-examination certificate.

Annex IV: Product Verification

A Notified Body tests the products in the final production phase, either by checking all products or by means of random samples on a statistical basis.

Annex V: Production Quality Assurance

The manufacturer has a quality management system for his production, testing and final inspection e.g. in compliance with EN ISO 13485:2003 (see Annex II).

Annex VI: Product Quality Assurance

The manufacturer has a quality management system for the final product inspection and testing (ISO 9003 and EN 46003, see Annex II).

Annex VII: Manufacturer Self Declaration

The manufacturer issues a conformity declaration without involving a Notified Body. He is, however, obliged to provide technical documentation, stating that the product fulfills the valid requirements, and he must have installed a system for market surveillance, reporting, document storage, etc.

National Variations

The conversion of the Directive into a national law allows several variations: such as language, registration of devices with the authorities and during operation.

In Germany the Directive was correspondingly converted on August 2, 1994 in the Medical Devices Law (MPG).

TÜV SÜD Product Service – Medical and Health Services. Your partner for medical product approval

TÜV SÜD Product Service provides you with comprehensive support in fulfilling the requirements arising from the Directive.

Thanks to our many years of experience and industry-specific expertise, we are able to cover all medical products and conformity evaluation procedures in accordance with AIMD (Directive on Active Implantable Medical Devices 90/385/EEC) and MDD (Medical Devices Directive 93/42/EEC). As the Notified Body for medical products, we have the identification number 0123.

You can attain the legally required examinations and certifications from us as well as benefiting from our extensive specialist knowledge in all development phase – worldwide. More than 1,000 customers around the globe trust in our competence, making us the market leader.

With 44 branch offices on all continents, Medical and Health Services supports you with fast, non-bureaucratic service. Our international cooperation enables us to provide you with access to additional markets such as those in North and South America, Australia, and the Asia-Pacific region.

With our voluntary test mark, the TÜV Octagon, Medical and Health Services also offers you the perfect emblem for presenting your competence in a publicly effective manner. Whether product testing, system certification, or a combination of both, the TÜV Octagon offers you the opportunity to showcase all of your quality efforts in just one symbol.

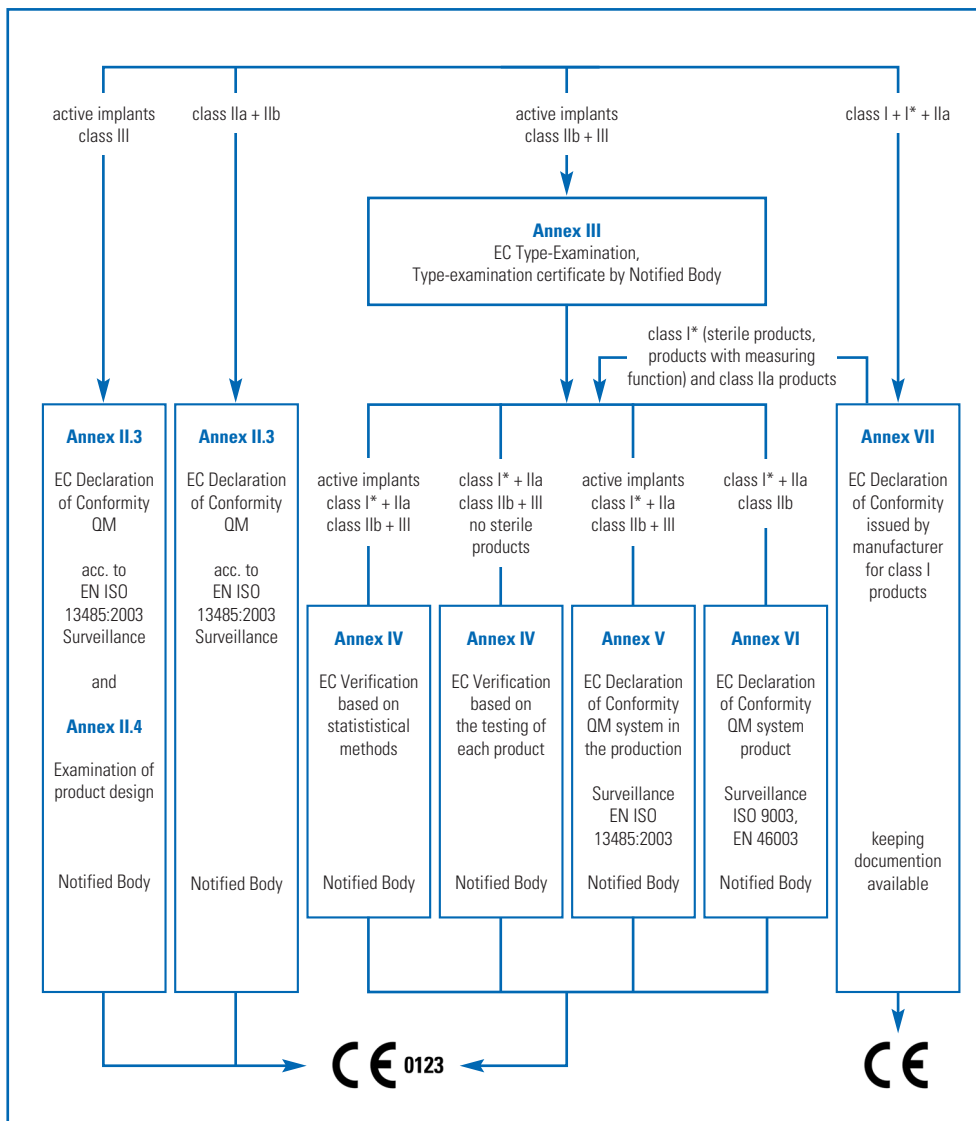
External Communication

You can use the TÜV mark on all business brochures, business cards or advertising, to name just some examples.

The TÜV mark is an international certification mark with voluntary testing to TÜV SÜD Product Service standards.

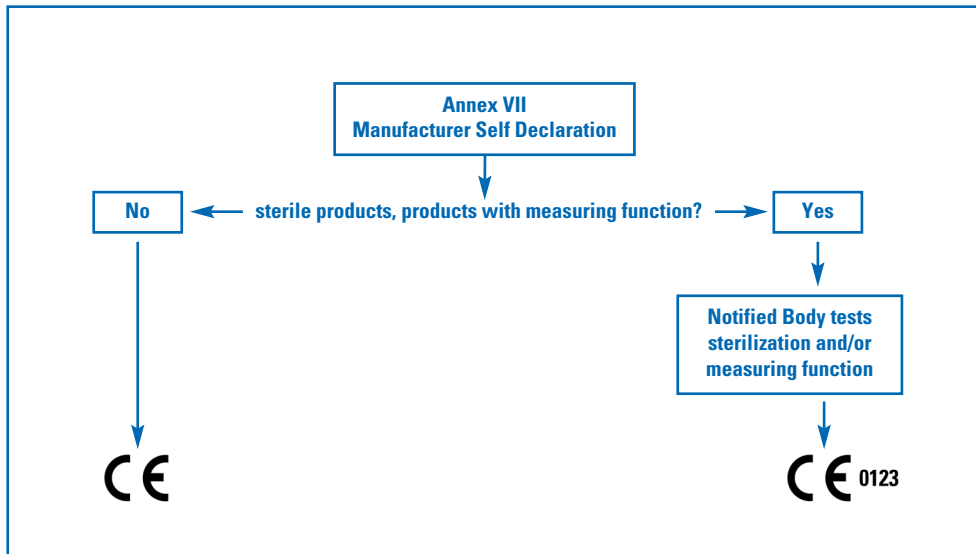


Survey of the various Conformity Assessment Procedures



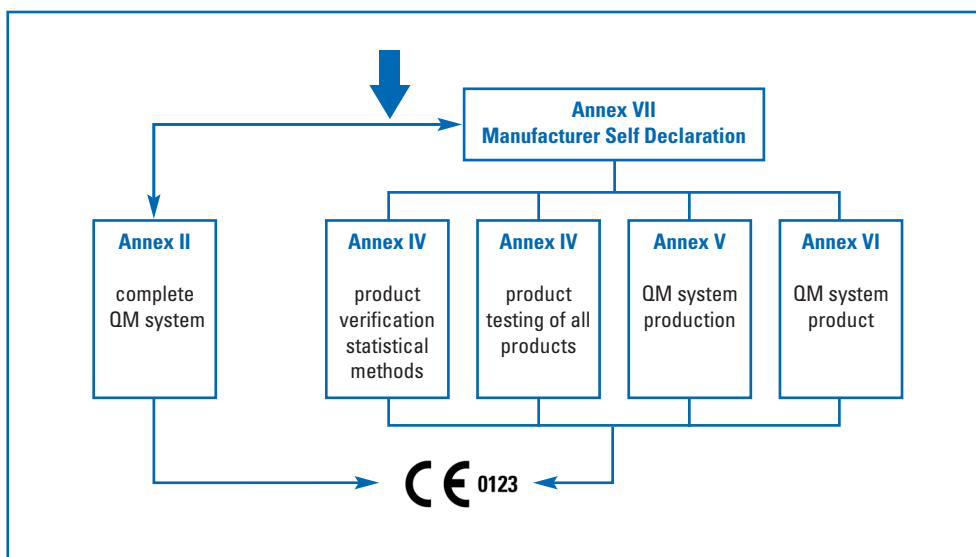
Conformity Assessment Procedure for Products in Class I

Examples: spectacle frames, walking aids



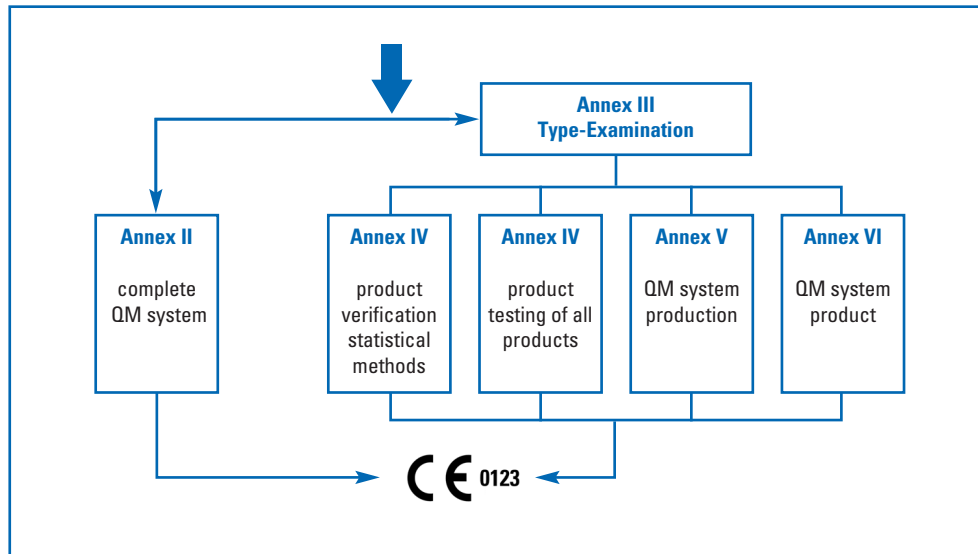
Conformity Assessment Procedure for Products in Class IIa

Examples: hearing aids, cannula



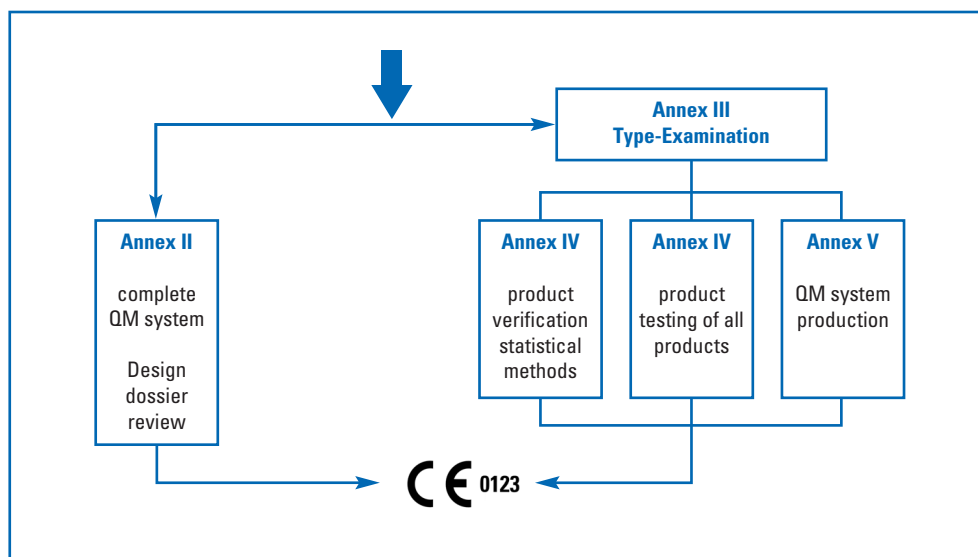
Conformity Assessment Procedure for Products in Class IIb

Examples: infusion pumps, blood bags, contact lenses



Conformity Assessment Procedure for Products in Class III

Examples: heart catheters, sewing material for use on the heart





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