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Council Directive 93/42/EEC on medical devices

Practice-oriented summary of the most important aspects and requirements contained in Directive 93/42/EEC incl. 2007/47/EC

What exactly is a medical device?

Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the following purposes:

- 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
- Conception control

Differentiation to medicines

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

What can be regarded as an accessory?

These articles are classified separately either as stand-alone product or as part of a medical device according to Annex IX of the Medical Devices Directive.

Exception to the rules

1. Custom-made devices, which are

- specifically made in accordance with a duly qualified medical practitioner's written prescription
- and are intended for the sole use of a particular patient.

2. Devices intended for clinical investigation.
   Those types of devices are falling under this Directive, but CE-marking is not possible.

Who is the manufacturer according to the Directive?

The Directive defines the manufacturer as the natural or legal person who is responsible for the design, manufacture, packaging and labelling of a medical device with regard to marketing in their own name, regardless of whether these actions are performed by that person or by a third party deputising for them. Manufacturers outside the EU require, in addition, a representative within the EU.

Essential requirements

Annex I of the Directive requires (examples):

- that the devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
- that the solutions adopted by the manufacturer for the design and construction of the devices conform to safety principles, taking account of the generally acknowledged state of the art.
- that the devices achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions as specified by the manufacturer.
- that the characteristics and performances of the devices are not adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
- that the devices are designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
- that any undesirable side effect does constitute an acceptable risk when weighed against the performances intended.
- that demonstration of conformity with the essential requirements include a clinical evaluation in accordance with Annex X.

In addition to these general requirements there are other requirements referring to the design:

- Chemical, physical and biological properties (toxicity, compatibility, etc.)
- Protection from infection and microbial contamination (processing, packaging)
- Features with regard to construction and the environmental conditions (minimising of risks)
- Measuring function (accuracy, displays)
- Protection against radiation (intentional or unintentional radiation, ionising 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 (labelling, instructions for use)
- Establishment of clinical data

Classification of medical devices by their risk 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 the 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 orifices
  - Surgically invasive
  - Implantable
- Location of use:
  - Central circulatory system
  - Central nervous system
  - Outside of both
- Energy supply:
  - Non-active
  - Active

Layout of Annex contents

Annex I:
Essential requirements

Annex II:
Full quality assurance system

The manufacturer has a quality management (QM) system, e.g. in compliance with EN ISO 13485, fulfils the additional requirements of the Directive (e.g. market surveillance, reporting, document storage, fulfilment of the essential requirements as laid down in Annex I), and declares the conformity of their products with the Directive. In the case of devices belonging to Class III, a product design review is also stipulated.

Annex III:
EC type examination

A notified body carries out a type examination according to the essential requirements of Annex I of the Directive and issues a type examination certificate.

Annex IV:
EC verification

A notified body tests the products after 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 (see Annex II). The requirements regarding design and development are excluded.

Annex VI:
Product quality assurance

The manufacturer has a quality management system for the final product inspection and testing, e.g. in compliance with EN ISO 13485 (see Annex II). The requirements regarding design and development, control of production and service provision, and validation of processes for production and service provision are excluded.

Annex VII:
EC declaration of conformity

The manufacturer issues a declaration of conformity without involving a notified body. They are, however, obliged to provide a technical documentation stating that the product fulfils the valid requirements, and must have installed a system for market surveillance (vigilance system), reporting, document storage, etc.

National variations

The transition of the Directive into national law allows several variations such as language, registration of devices with the authorities and requirements for operation.

In Germany, the Directive was correspondingly converted on 2 August 1994 in the German Act on Medical Devices (MPG). This was last amended on 18 July 2017.

Within the scope of this amendment, the following decision was made: in future, only the higher federal authority will be allowed to decide on disputes between the manufacturer and the notified body on the following aspects:

1. Application of the above rules
2. Differentiation between medical devices and other products
3. Classification of whether medical devices in Class I are medical devices with a measuring function or placed on the market in sterile condition

In all of these cases the notified body must contact the higher federal authority.

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

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

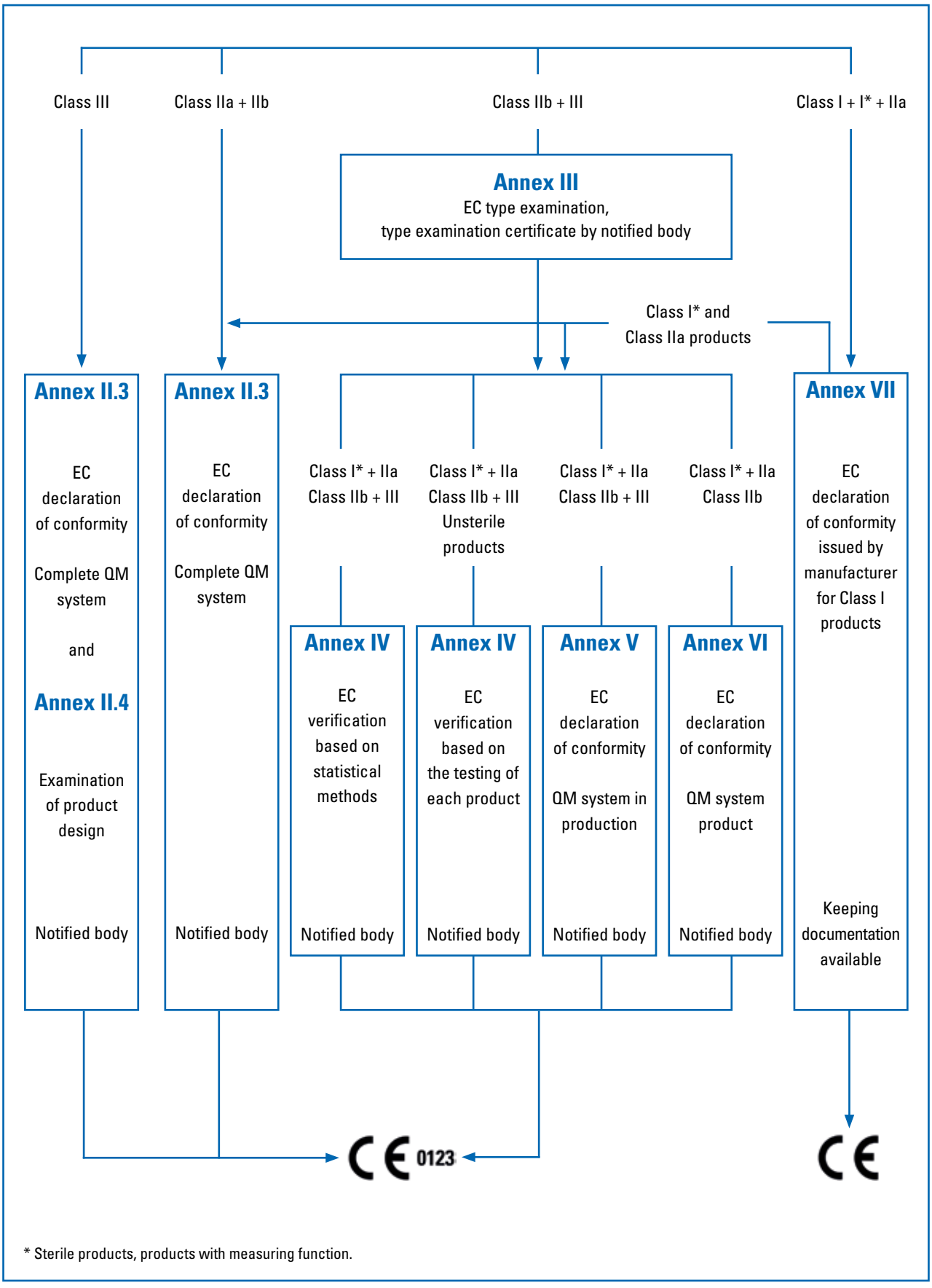
A long-standing experience and industry-specific know-how enable us to cover all medical devices and conformity assessment procedures in accordance with Directive on Medical Devices 93/42/EEC (MDD), Directive on Active Implantable Medical Devices 90/385/EEC (AIMDD), and Directive on In vitro Diagnostic Medical Devices 98/79/EC (IVDD). As notified body for medical devices, our identification number is 0123.

We are able to provide you with the legally required testing and certification services; you can profit from our comprehensive expertise – worldwide. More than 1,000 customers around the world trust in our competence and thus make us the world leader.

With more than 44 branches on all continents, TÜV SÜD Product Service provides support through fast, customer-focussed service. Our international cooperations give you access to further markets, e.g. North and South America, Australia, and the Asia-Pacific region.

With our voluntary TÜV SÜD certification mark, you emphasise your competence also in public.

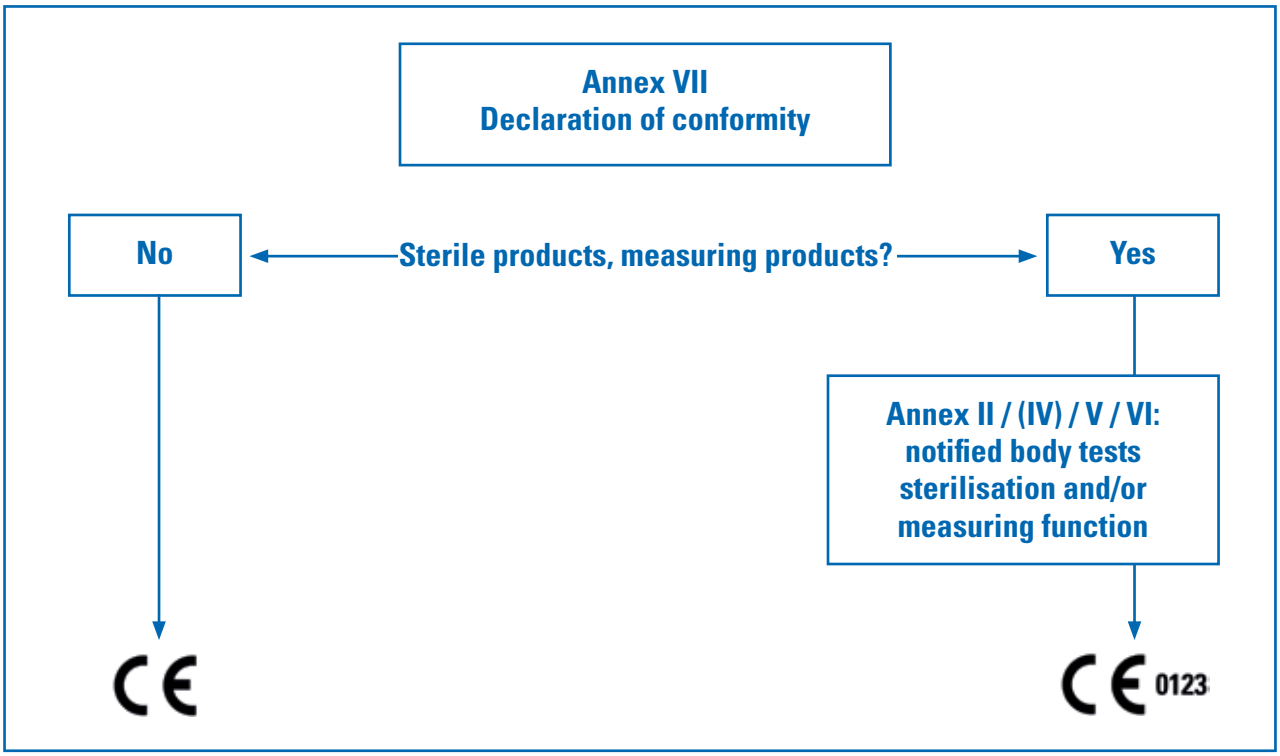
Survey of the various conformity assessment procedures



* Sterile products, products with measuring function.

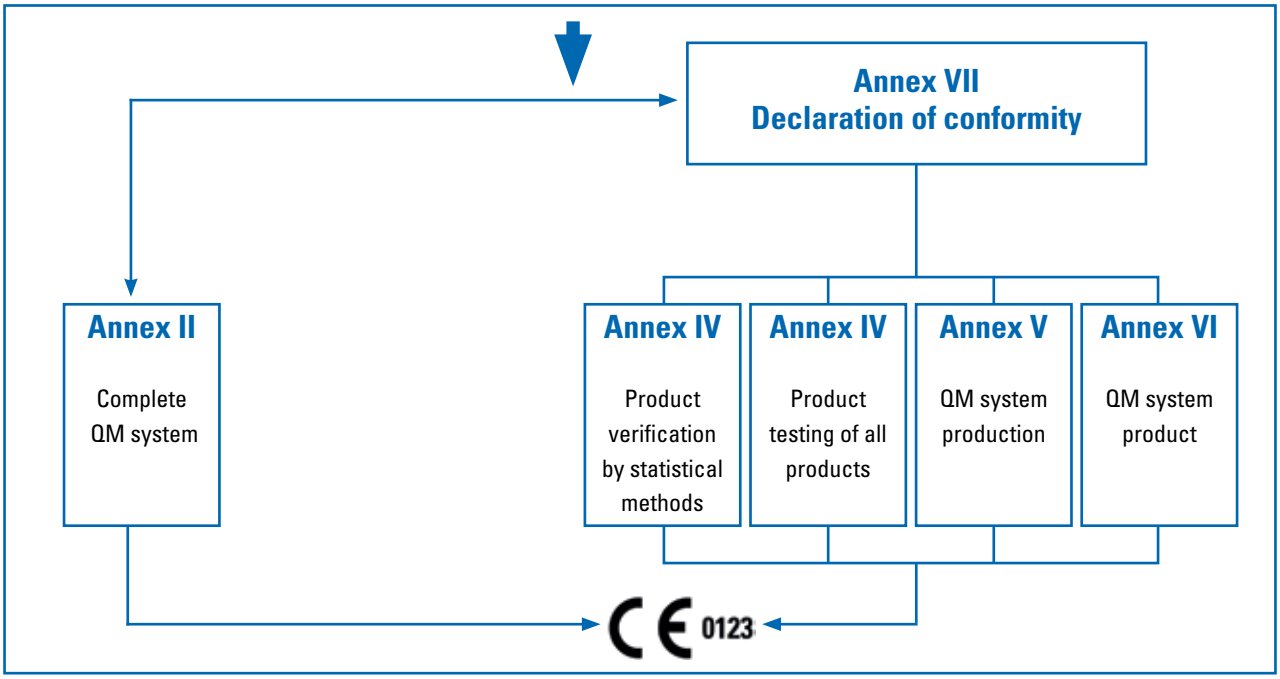
Conformity assessment procedure for Class I devices

Examples: Spectacle frames, walking aids



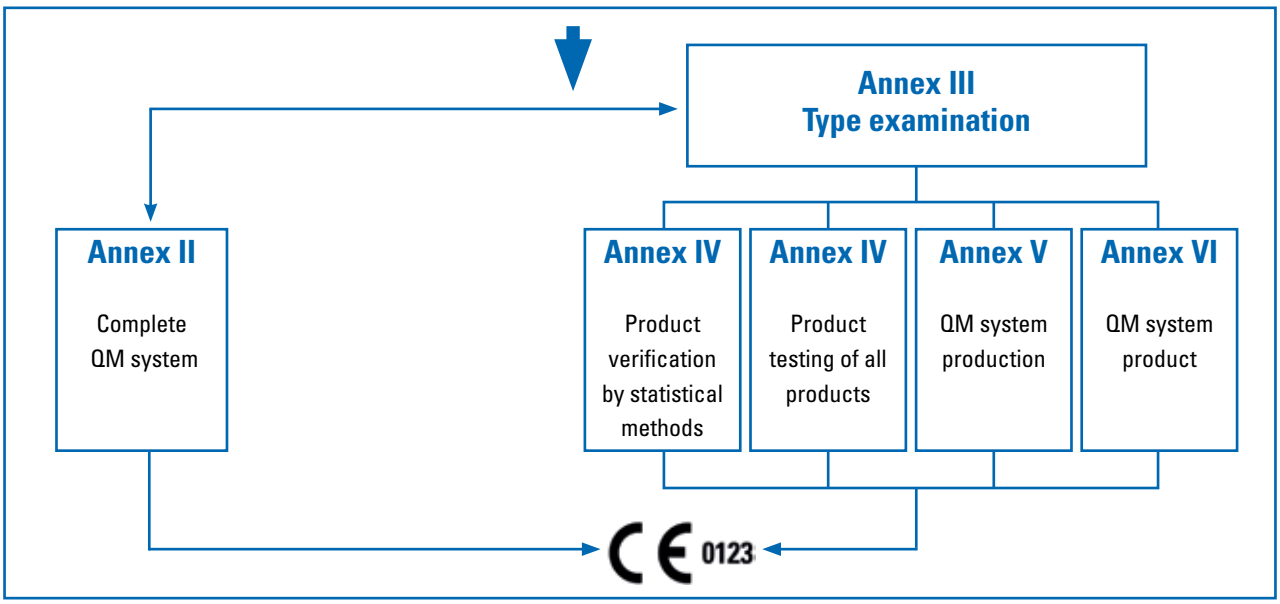
Conformity assessment procedure for Class IIa products

Examples: Hearing aids, cannulas



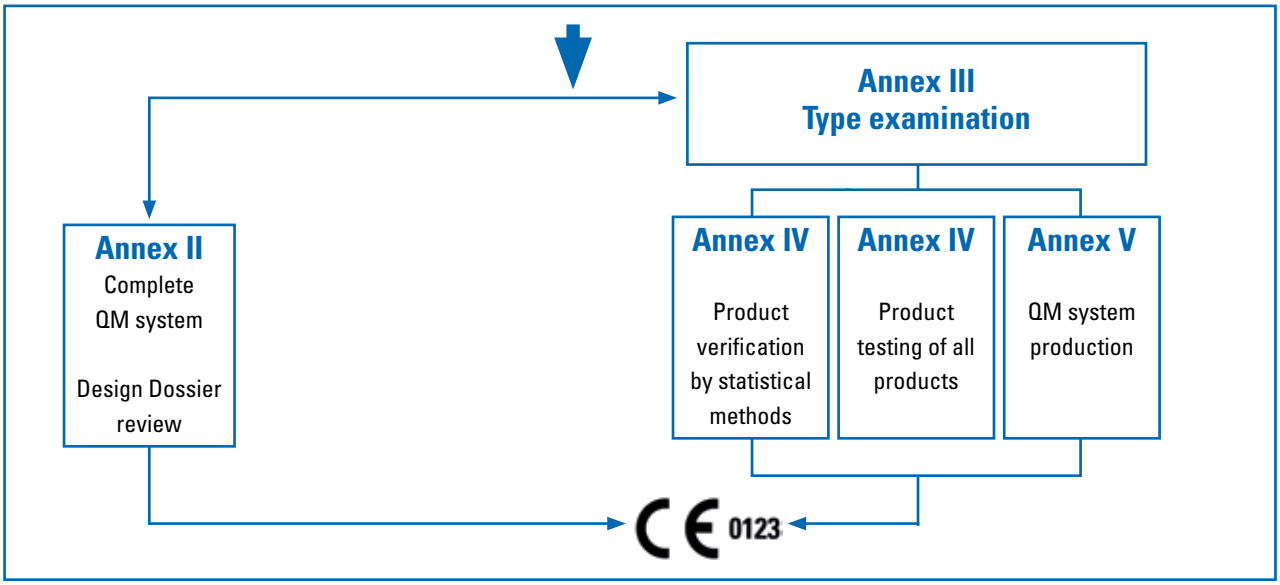
Conformity assessment procedure for Class IIb devices

Examples: Infusion pumps, blood bags, contact lenses



Conformity assessment procedure for Class III devices

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



Your contact partner at TÜV SÜD Product Service can provide further information.

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