

Directive 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Practice-oriented summary of the most important aspects and requirements

In vitro diagnostic medical devices are subject to the European Directive 98/79/EC (IVDD). Presenting a subgroup of medical products, their market access, use, and market surveillance is regulated. The Directive is implemented in the national laws of the member states.

What are in vitro diagnostic medical devices (IVDs)?

According to the Directive, in vitro diagnostic medical devices include: reagents, reagent products, calibration materials, control materials, kits, instruments, apparatus, equipment, and systems that are intended for use in the examination of specimens taken from the human body (tissue, blood, urine, etc.) to diagnose diseases, to monitor a person's physiological state, or to monitor therapeutic procedures.

Examples of in vitro diagnostic medical devices are:

- hepatitis or HIV tests
- clinical chemical tests
- coagulation test systems
- urine test strips
- pregnancy tests
- blood sugar monitoring systems for diabetics
- receptacles manufactured specifically for medical specimens

Accessories

Accessories include items that themselves are not in vitro diagnostic medical devices but are intended for use with those devices. Under the Directive, accessories are treated as separate in vitro diagnostic medical devices.

Devices for self-testing

Devices for self-testing form a special IVD group. These IVDs are intended by the manufacturer to be used by laypersons in a home environment, for example pregnancy tests.

Devices for performance evaluation

Devices to be used in performance evaluation studies outside the manufacturer's facility are also covered by the Directive.

Exceptions

Products that are used only for veterinary medicine as well as products for general laboratory use are not subject to the IVD Directive. However, sampling devices that are either invasive or come into contact with patients are subject to Directive 93/42/EEC on medical devices.

Who is a 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 finished device for the purpose of marketing under his/her own name, regardless of whether these activities are performed by that person or

by a third party acting on his/her behalf. The impact of the Directive on suppliers of semifinished goods is indirect. Manufacturers of finished IVD products outside the EU must have a representative within the EU.

Essential requirements for in vitro diagnostic medical devices

Annex I of the Directive requires that the safety and health of patients, users, and any third party must not be endangered by proper use of the product and that any possible product risk – compared with the associated benefit – is acceptable.

The principle of integrated safety applies, i.e.

risk avoidance and risk minimization in the design and manufacture of the product, protective measures against residual risks, and appropriate information for users. The generally acknowledged state of the art must be applied. The product must be suited for the intended use and the assigned performance characteristics ensured for the lifetime of the product.

In addition to these general requirements, there are other requirements that apply above all to the design and manufacture of the devices and refer to:

- chemical and physical characteristics (compatibility with the material to be tested)
- protection against infection and microbial contamination (processing, packaging)
- suitability for use under the respective environmental conditions (risk minimization)
- combination with other products, disposal
- measurement function (precision, display)
- protection against radiation (intentional or non-intentional radiation, ionizing radiation)
- protection against electrical shocks, electromagnetic compatibility
- protection against mechanical or thermal risks
- use by laypersons: easy to use, low risk of incorrect interpretation of results (products for self-testing only)
- provision of information by the manufacturer (labeling, instructions)

The requirements are further detailed and explained in

- harmonized standards, e.g. ISO EN 14971
- common technical specifications (Annex II devices only)
- guidance documents, e.g. MEDDEV documents

Product Groups

The Directive distinguishes four different groups – based on the risk associated with the use of the respective products.

List A

List A of Annex II contains the products with the highest potential risk. These include reagents, calibrators and controls for the determination of

- blood groups (ABO system, rhesus, and anti-Kell)
- HIV-1/-2 infections, HTLV-I/-II infections, and hepatitis B, C, and D.

List B

List B of Annex II contains high risk products (reagents, calibrators and controls unless otherwise stated):

- for the determination of blood groups (anti-Duffy and anti-Kidd)
- for determination of irregular anti-erythrocytic antibodies
- for the detection of rubella and toxoplasmosis
- for the diagnosis of phenylketonuria
- for the detection of infections with cytomegalovirus or chlamydia
- for the determination of the tumor marker PSA
- for the determination of HLA tissue types DR, A, B
- for the evaluation of the risk of trisomy 21, including software
- products for self-testing of blood sugar levels including instruments

All products in List A and List B require the participation of a Notified Body in all aspects of the conformity assessment procedure.

Devices for self-testing

These are subject to special requirements, which are described in Annex I, Section 7 of the Directive:

- The product must be easy to use for laypersons, and the enclosed instructions must be easy to understand.
- The risk of errors in use or in the interpretation of results must be kept as low as possible.
- Where possible, such devices must include a user control which allows verification of correct performance at the time of use.

A typical example is a pregnancy test.

Devices for self-testing require participation of a Notified Body in the conformity assessment. The aspect of self-testing is of special interest in the evaluation by the Notified Body.

Note: Products for determining blood sugar levels are exempted from this device group (see List B).

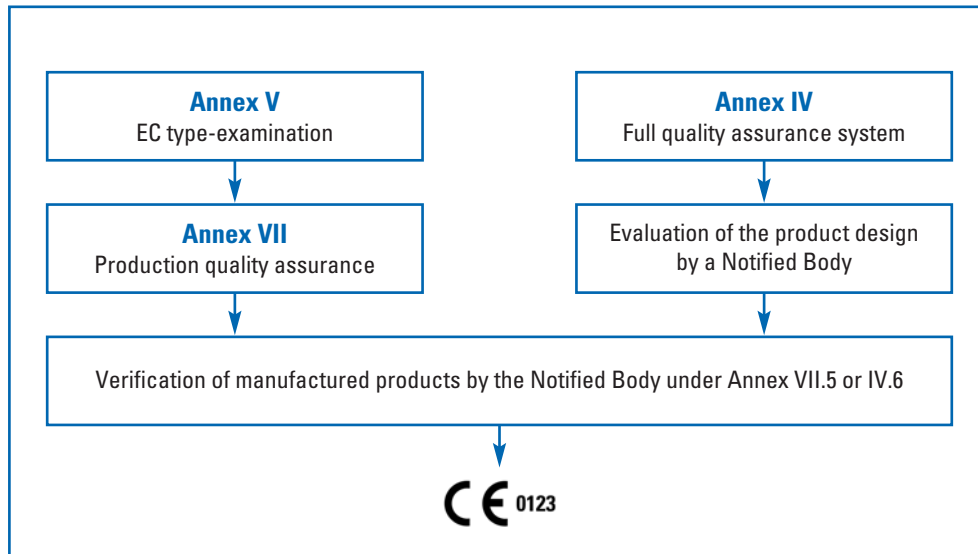
Other IVD products

Products that are neither listed in Annex II nor intended for self-testing do not require involvement of a Notified Body in the conformity assessment. Typical examples are clinical chemistry tests or tests for thyroid function.

If you have any questions concerning conformity assessment procedures for your products, our experts will be pleased to help you.

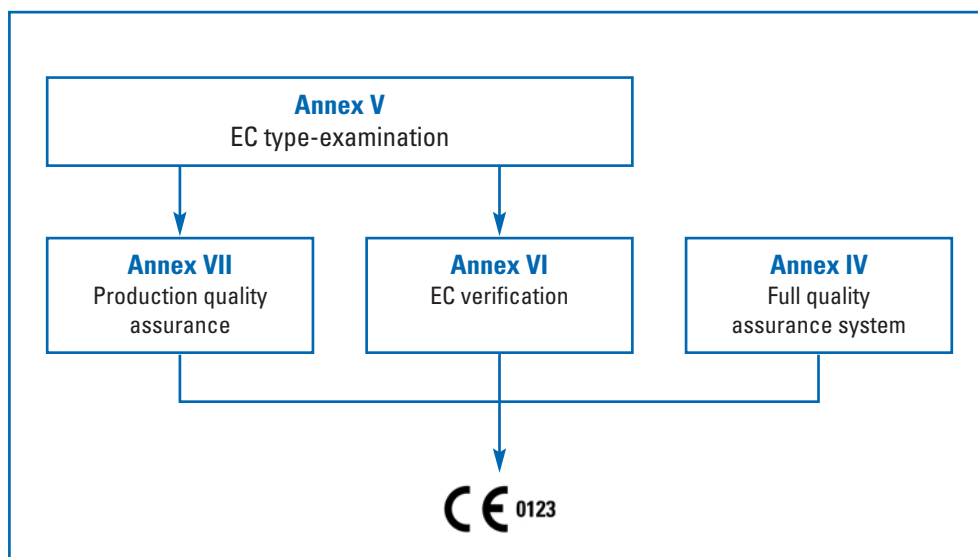
Conformity Assessment Procedure for List A Products

Example: HIV test kit



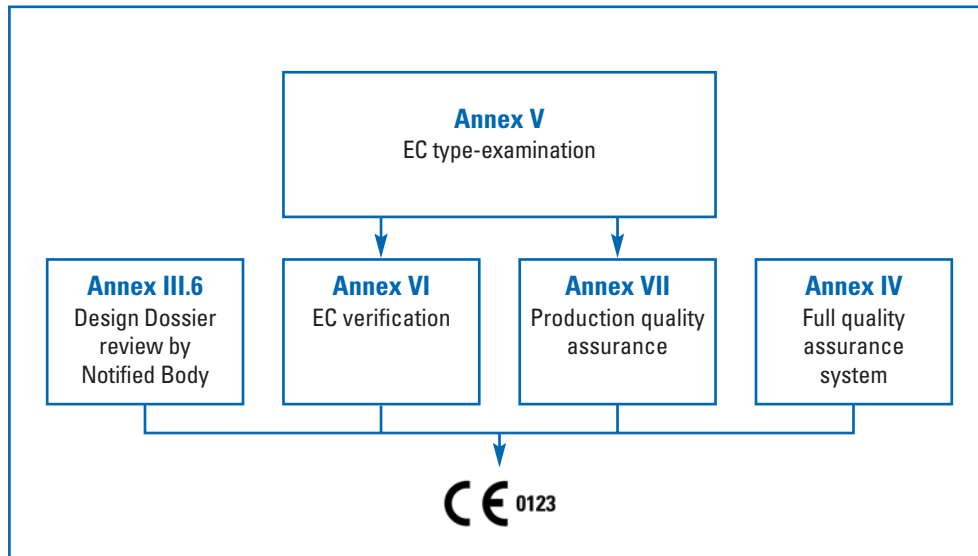
Conformity Assessment Procedure for List B Products

Example: Tumor marker PSA



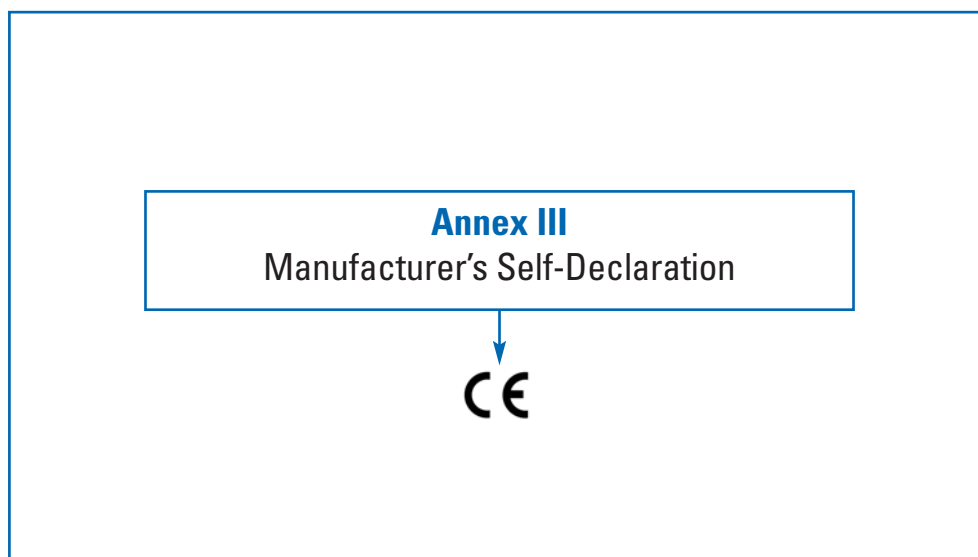
Conformity Assessment Procedure for Devices for Self-Testing

Example: Pregnancy test



Conformity Assessment Procedure for Other IVDs

Example: Blood sugar test by trained medical personnel



Overview of Annexes III-VIII

Annex III: Manufacturer's Self-Declaration

The manufacturer must compile and maintain a technical documentation showing that the product meets the applicable requirements. The manufacturing process must comply with the principles of quality assurance. A system for market surveillance, reporting, document storage, etc. must be in place. After successful self-assessment without participation of a Notified Body the manufacturer issues a declaration of conformity.

Annex III.6

Assessment of the technical documentation of self-testing devices by the Notified Body, to be performed in addition to Annex III if this way is chosen. No audit required.

Annex IV: Full quality assurance system

The manufacturer has a full quality management system (ISO 13485 including design), fulfills the additional requirements of the Directive (e.g. Annex I), and declares the conformity of his products with the Directive. These measures are assessed in initial and surveillance audits by a Notified Body. In addition, List A devices require a product design examination according to Annex IV.4 and verification of manufactured products according to Annex IV.6 by the Notified Body, focussing on lot-to-lot consistency.

Annex V: EC type-examination

A Notified Body conducts a type evaluation to check the compliance of the prototype with

the essential requirements of Annex I of the Directive and issues a type examination certificate.

In addition, List A devices require a verification of manufactured products according to Annex VII.5, focussing on lot-to-lot consistency.

Annex VI: EC verification

A Notified Body tests the finished products. Each product batch is tested and released individually (not applicable to List A products).

Annex VII: Production quality assurance

The manufacturer has a quality management system for production, testing, and final inspection (ISO 13485) and meets the additional requirements of the Directive (Annex I).

Annex VIII: Devices for performance evaluation

Obligations of the manufacturer including the contents of a statement to be issued for respective products are defined in this Annex.

National implementation

The Directive on In Vitro Diagnostic Medical Devices was issued by the European Parliament and the Council of the European Union on 27 October 1998, and was published in the Official Journal of the EU on 7 December 1998. The Directive came into effect on 7 June 2000.

TÜV SÜD Product Service: Your Partner for Testing and Certification

A longstanding experience and industry-specific know-how enable us to cover all medical products and conformity assessment procedures in accordance with AIMD (Directive for Active Implantable Medical Devices 90/385/EEC), MDD (Directive on Medical Devices 93/42/EEC), and IVDD (Directive on In Vitro Diagnostic Medical Devices 98/79/EC). As Notified Body for medical products, our certification body number is 0123.

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Whether product testing, system certification, or a combination of both, the TÜV SÜD Octagon represents a symbol of your efforts to achieve quality in all areas.

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In the area of in vitro diagnostic medical devices, we work with a network of highly qualified partners who have to meet your and our quality criteria. By always working with the most qualified partners, we ensure that our service to you is always state-of-the-art.



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