

Conformity Assessment

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Declaration of Conformity

In Annex II, V and VI, Directive 93/42/EEC on medical devices requires that the manufacturer must affix the CE-marking according to article 17 and draw up a written Declaration of Conformity. This declaration must cover a given number of products manufactured (Annexes II, V and VI, articles 2).

How is the „given number“ to be interpreted?

The manufacturer or his authorised representative established in the European Community is obliged to issue an EC Declaration of Conformity with the product is in a conformity assessment procedure required by the Directive on medical devices before placed on the market.

With the Declaration of Conformity the manufacturer declares that the products concerned meet the relevant provisions of the applicable directives or the type described in the type examination certificate, respectively.

The content of the EC Declaration of Conformity is determined in each directive. Guidance on the contents of the declaration of conformity can be found, inter alia, in the „Guide to the implementation of directives based on the New Approach and the Global Approach“ [1] and the standard EN ISO/IEC 17050-1 [2].

The declaration of conformity according to directive 93/42/EEG should contain at least the following contents:

- the name and address of the manufacturer or his authorised representative
Where procedures according to Annex II or VII in connection with IV, V or VI are applied, the obligation to draw up the declaration of conformity lies exclusively with the manufacturer (see e.g. 93/42/EEG appendix VII Abs. 6.1).
- the EC directive(s) and their Annexes, after which the conformity is declared
- a statement that the manufacturer is exclusively responsible for the declaration of conformity
- object of the declaration: Data to the product (name, design/type or model number)
- number of products, the declaration of conformity refers to (e.g. lot, batch, or serial numbers, numbers of items)

As an alternative to the indication of lot, batch or serial numbers, the clear reference to the products covered by the declaration of conformity can be established via the validity period of the declaration of conformity, which is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the certificate(s) issued by the notified body.

- additional information (e.g. applied standards, normative documents)
Optionally; if standards are referenced, all applicable parts of the standards must be fulfilled.
- place and date of the declaration of conformity
- legally binding signature and function of the authorised person
- name, address and identification number(s) of notified bodies being involved in the conformity assessment procedure

If several EC directives are applicable in parallel, it must be recognizable, which notified body is assigned to which directive. If the conformity assessment presupposes the engagement of more than one notified body in the production phase or, if required by the directives, the CE marking on the product shall be followed by the identification numbers of these bodies.

The drawing up of the declaration of conformity is an essential element of a quality assurance system – see e.g. harmonized standard EN ISO 13485 : 2003 section 4.2.1 –, which is to be audited by the notified body at least with procedures according to Annex II. It make sense to consider the declaration of conformity as a part/component of the technical documentation. Both the technical documentation and the declaration of conformity should be subject to appropriate measures of document and record control. The declaration of conformity is to be kept at the disposal of the national authorities for a period ending at least five years after the last product has been manufactured.

Reference	93/42/EEC article 11 and Annex II, V and VI
Sources	[1] Guide to the implementation of directives based on the New Approach and the Global Approach (1999) [2] EN ISO/IEC 17050-1 : 2004 Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements EN ISO/IEC 17050-2 : 2004 Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation
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