

ANNEX 2

EC DECLARATION OF CONFORMITY
(Complete quality assurance system)

3. Quality system

3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application shall include:

- all the appropriate items of information for the category of products manufacture of which is envisaged,
- the quality-system documentation,
- an undertaking to fulfil the obligations arising from the quality system as approved,
- an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,
- ^[F1]an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7.] The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;
 - (ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

Textual Amendments

- F1** Substituted by [Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market \(Text with EEA relevance\).](#)

3.2. The application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final controls.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.^[F2] It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).]

Textual Amendments

- F2** Inserted by [Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating](#)

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to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

It shall include in particular an adequate description of:

- (a) the manufacturer's quality objectives;
 - (b) the organization of the business and in particular:
 - the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the products, including control of products which do not conform^[F1],
 - ^[F2]where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;
 - (c) the procedures for monitoring and verifying the design of the products and in particular:
 - the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards referred to in Article 5 are not applied in full,
 - the techniques of control and verification of the design, the processes and systematic actions which will be used when the products are being designed^[F1],
 - ^[F2]a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
 - the pre-clinical evaluation,
 - the clinical evaluation referred to in Annex 7;
 - (d) the techniques of control and of quality assurance at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (e) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.
- 3.3. Without prejudice to Article 13 of this Directive, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. ^[F1]The evaluation procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.]

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.