

ANNEX V

EC DECLARATION OF CONFORMITY

(Production quality assurance)

1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the Community surveillance referred to in Section 4.
2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meets the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover a given number of identified specimens of the products manufactured and must be kept by the manufacturer.

3. **Quality system**

- 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer,
- all the relevant information on the product or product category covered by the procedure,
- a written declaration that no application has been lodged with any other notified body for the same products,
- the documentation on the quality system,
- an undertaking to fulfil the obligations imposed by the quality system **is approved**,
- an undertaking to maintain the practicability and effectiveness of the **approved quality system**,
- where appropriate, the technical documentation on the types **approved and a copy of the EC type-examination certificates**,
- an undertaking by the manufacturer to institute and keep up to date a **systematic procedure** to review experience gained from devices in the post-production phase and to **implement appropriate means** to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents **immediately on learning of them**:
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.

- 3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must 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 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 product, including control of products which fail to conform;
- (c) the inspection and quality assurance techniques at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

- 3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment.

- 3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2.

After the abovementioned information has been received the decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

- 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.
- 4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with all relevant information, in particular:
 - the documentation on the quality system,
 - the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.
- 4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

- 5.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, make available to the national authorities:

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- the declaration of conformity,
 - the documentation referred to in the fourth indent of Section 3.1,
 - the changes referred to in Section 3.4,
 - the documentation referred to in the seventh indent of Section 3.1,
 - the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,
 - where appropriate, the type-examination certificate referred to in Annex III.
- 5.2. The notified body must make available to the other notified bodies, on request, all relevant information concerning the quality system approvals issued, refused or withdrawn.
6. **Application to devices in Class IIa**
- In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following exemption:
- 6.1. in derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.
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