

ANNEX VI

EC DECLARATION OF CONFORMITY

(Product quality assurance)

1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3 and must be subject to the surveillance referred to in Section 4.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 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 meet the provisions of this Directive which apply to them.

The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover a given number of identified specimens of the products manufactured and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

3. **Quality system**

- 3.1. The manufacturer lodges 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 specifying that no application has been lodged with any other notified body for the same products,
- the documentation on the quality system,
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
- 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 the performance of a device for the reasons referred to in subparagraph (i) leading to a systematic recall of devices of the same type by the manufacturer.

- 3.2. Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of this Directive which apply to them. All the elements, requirements and provisions

adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It must include in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality,
- the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately,
- the methods of monitoring the efficient operation of the quality system
- the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

- 3.3. The notified body audits 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. It must 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 will still meet the requirements referred to in Section 3.2.

After receiving the abovementioned information it must notify the manufacturer of its decision. This decision 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 must allow the notified body access for inspection purposes to the inspection, testing and storage locations and supply it with all relevant information, in particular:

- the documentation on the quality system,
- the technical documentation,
- the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.

- 4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must 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 and that the production conforms to the requirements of the Directive which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out. Where one or more of the samples fails to conform, the notified body must take the appropriate measures.

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:
- the declaration of conformity,
 - the documentation referred to in the seventh indent of Section 3.1,
 - the changes referred to in Section 3.4,
 - the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,
 - where appropriate, the certificate of conformity 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 this derogation:

- 6.1. by 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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