ANNEX 5

EC DECLARATION OF CONFORMITY TO TYPE
(Assurance of production quality)

1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in 3; he shall be subject to the surveillance referred to in section 4.

2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of section 1 guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of the Directive which apply to them.

[[F1]The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more **[**[F2]devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer**]**. The CE marking shall be accompanied by the identification number of the notified body responsible.**]**

Textual Amendments

F1 Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).

F2 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. 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 appropriate information concerning the products which it is intended to manufacture,

— 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,

— where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate,

— an undertaking by the manufacturer to institute and keep up-dated a **[**[F2]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.

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 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.

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 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[X1 of the design and] of the products, including control of products which do not conform[F2,]
- [F3 where the manufacture and/or final inspection and testing of the products, or elements thereof, are 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 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;

(d) 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.

Editorial Information

X1 Deleted by Corrigendum to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (Official Journal of the European Communities No L 189 of 20 July 1990).

Textual Amendments

F3 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

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).

3.3. Without prejudice to Article 13, 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. The evaluation procedure shall include an inspection on the manufacturer's premises.

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 that 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.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4.2. The manufacturer shall authorize the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

— the quality-system documentation,

— **[**[F3]the technical documentation,**]**

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

4.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

4.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

5. The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

[[F3]6. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.**]**