ANNEX VII

EC DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)

1. The manufacturer must ensure application of the quality system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in section 3, and is subject to the 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 meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 16 and draw up a declaration of conformity covering the devices concerned.

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 technical documentation on the types approved and a copy of the EC type-examination certificates.

3.2. Application of the quality system must ensure that the devices 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 organisation of the business and in particular:
- — the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of manufacture of the devices 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 devices 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 sterilisation,
- — the procedures in relation to purchasing,
- — 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 to trace back the calibration.

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 harmonised standards conform to these requirements.

The assessment team must have 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 and/or subcontractors 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 shall 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. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

The provision of Annex IV, section 5, shall apply.

5. Verification of manufactured products covered by Annex II, List A

5.1. In the case of devices covered by Annex II, List A, the manufacturer shall forward to the notified body without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on the manufactured devices or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities.

5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.