ANNEX III

EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Directive.

2. The application includes:

— the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative,

— the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Directive. The applicant must make a 'type' available to the notified body. The notified body may request other samples as necessary,

— a written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

— a general description of the type, including any variants planned,

— design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,

— the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,

— a statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex I and data on the tests conducted in this connection,

— the clinical data referred to in Annex X,

— the draft label and, where appropriate, instructions for use.

4. The notified body must:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant on the place where the necessary inspections and tests will be caried out.

5. If the type conforms to the provisions of this Directive, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

In the case of devices referred to in Annex I, paragraph 7.4, the notified body shall, in view of the aspects addressed in that paragraph, consult one of the competent bodies established by the Member States in accordance with Directive 65/65/EEC before taking a decision.

The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

6. The applicant must inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

7.1. The notified body must make available to the other notified bodies on request, all relevant information on EC type-examination certificates and supplements issued, refused or withdrawn.

7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed.

7.3. The manufacturer or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured.

7.4. When neither the manufacturer nor his authorized representative is established in the Community, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the Community market or the importer referred to in Annex I, Section 13.3 (a).