ANNEX III

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by section 2 to 5 and additionally, in the case of devices for self-testing, the obligations imposed by section 6, ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 16.

2. The manufacturer must prepare the technical documentation described in section 3 and ensure that the manufacturing process follows the principles of quality assurance as set out in section 4.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:

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

   — the documentation of the quality system,

   — design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits, etc.,

   — in the case of devices containing tissues of human origin or substances derived from such tissue, information on the origin of such material and on the conditions in which it was collected,

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

   — the results of the risk analysis and, where appropriate, 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 of the Directive if the standards referred to in Article 5 have not been applied in full,

   — in the case of sterile products or products with a special microbiological state or state of cleanliness, a description of the procedures used,

   — the results of the design calculations and of the inspections carried out, etc.,

   — if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when combined with any such device(s) having the characteristics specified by the manufacturer,

   — the test reports,

   — adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used; such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references,

   — the labels and instructions for use,

   — the results of stability studies.

4. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured.

   The system shall address:

   — the organisational structure and responsibilities,

— the manufacturing processes and systematic quality control of production,

— the means to monitor the performance of the quality system.

5. The manufacturer shall 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 actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:

(i) any malfunction, failure 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, directly or indirectly, might lead to, or might have led to, the death of a patient or user or other persons or to a serious deterioration in his or their 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 systematic recall of devices of the same type by the manufacturer.

6. For devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.

6.1. The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of the directive to be assessed.

It shall include:

— test reports including, where appropriate, results of studies carried out with lay persons,

— data showing the handling suitability of the device in view of its intended purpose for self-testing,

— the information to be provided with the device on its label and its instructions for use.

6.2. The notified body shall examine the application and, if the design conforms to the relevant provisions of this Directive shall issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the design-related requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

6.3. The applicant shall inform the notified body which issued the EC design-examination certificate of any significant change made to the approved design. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. This additional approval shall take the form of a supplement to the EC design-examination certificate.