ANNEX VIII

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative established in the Community must draw up the statement containing the information stipulated in Section 2.

2. The statement must contain the following information:

2.1. for custom-made devices:

— data allowing identification of the device in question,

— a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,

— the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,

— the particular features of the device as specified in the relevant medical prescription,

— a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;

2.2. for devices intended for the clinical investigations covered by Annex X:

— data allowing identification of the device in question,

— an investigation plan stating in particular the purpose, scientific, technical or medical grounds, scope and number of devices concerned,

— the opinion of the ethics committee concerned and details of the aspects covered by its opinion,

— the name of the medical practitioner or other authorized person and of the institution responsible for the investigations,

— the place, starting date and scheduled duration for the investigations,

— a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer must also undertake to keep available for the competent national authorities:

3.1. for custom-made devices, documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

3.2. for devices intended for clinical investigations, the documentation must contain:

— a general description of the product,

— 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,

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

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

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section.

The manufacturer must authorize the assessment, or audit where necessary, of the effectiveness of these measures.

4. The information contained in the declarations concerned by this Annex should be kept for a period of time of at least five years.