ANNEX III

EC DECLARATION OF CONFORMITY

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.