ANNEX 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

2. The statement shall comprise the following information:

2.1. For custom-made devices:

— **[**F1the name and address of the manufacturer,

— the information necessary for the identification of the product in question,**]**

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

— the name of the **[**F1duly qualified medical practitioner**]** who drew up the prescription and, if applicable, the name of the clinic concerned,

— **[**F1the specific characteristics of the product revealed by the prescription,**]**

— a statement affirming that the device complies with the essential requirements given in Annex 1 and, where applicable, indicating which essential requirements have not been wholly met, together with the grounds.

Textual Amendments

F1 Substituted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

[F1 2.2. For devices intended for clinical investigations covered in Annex 7:

— data allowing the devices in question to be identified,

— the clinical investigation plan,

— the investigator's brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1,

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

— the name of the duly qualified medical practitioner or other authorised person and of the institution responsible for the investigations,

— the place, date of commencement and duration scheduled for the investigations,

— a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.**]**