

ANNEX VIII

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

2. The statement must contain the following information:
 - 2.1. for custom-made devices:
 - ^[F1]the name and address of the manufacturer,]
 - 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,
 - ^[F2]the specific characteristics of the product as indicated by the 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;

Textual Amendments

- F1** Inserted 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 \(Text with EEA relevance\).](#)
- F2** 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 \(Text with EEA relevance\).](#)

- 2.2. for devices intended for the clinical investigations covered by Annex X:
 - data allowing identification of the device in question,
 - ^[F2]the clinical investigation plan,]
 - ^[F1]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 7.4 of Annex I,
 - a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,]
 - 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.