**ANNEX IV**

**EU declaration of conformity**

**The EU declaration of conformity contains all of the following information:**

**1. The name, company name or registered trade mark, and, if already issued, the unique registration number refered to in Article 31 of the manufacturer and, where applicable, of his authorized representative, and address of their head office at which they can be reached and that of their place of establishment.**

**2. A certificate certifying that the EU declaration of conformity is drawn up under the sole responsibility of the manufacturer.**

**3. The basic UDI-ID referred to in Annex VI part C.**

**4. The name and trade name of the product, the product code, the number in the catalog or another unambiguous reference allowing the identification and the traceability of the device which is the subject of the EU declaration of conformity, such as a photo, if necessary, as well as its destination. With the exception of the name or the trade name of the product, the information allowing identification and traceability may be contained in the basic UDI-ID referred to in point 3.**

**5. The risk class of the device in accordance with the rules set out in Annexe VIII.**

**6. A declaration that the device which is the subject of the EU declaration of conformity complies with this Regulation and, where applicable, any other applicable Union legislation providing for the establishment of an EU declaration of conformity.**

**7. References to the common specifications which have been used and against which conformity is declared.**

**8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure followed and the reference of the certification (s) issued.**

**9. Where appropriate, additional information.**

**10. The place and date of issue of the delaration, the name and function of the signatory as well as the name pf the person on whose behalf the latter has signed, and the signature.**