STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Procedures for custom-made active implantable medical devices

28. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

(a) has drawn up the statement containing the information required by Section 2.1 of Annex 6;

(b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;

(c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex 6; and

(d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).