STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Procedures for custom-made general medical devices

15. 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 a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII;

(b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and

(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 VIII; and

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