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## STATUTORY INSTRUMENTS

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# 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; <sup>F1</sup>...
- (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) [<sup>F2</sup>; and
- (e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.]

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##### **Textual Amendments**

- F1** Word in reg. 15(c) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **8(1)**
- F2** Reg. 15(e) and word inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **8(2)**

**Status:**

Point in time view as at 21/03/2010. This version of this provision has been superseded.

**Changes to legislation:**

The Medical Devices Regulations 2002, Section 15 is up to date with all changes known to be in force on or before 11 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.