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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 affixing a CE marking to general medical devices**

**13.**—(1) A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by Annex VII;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(2) A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex VII, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex III, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, or
  - (ii) Annex III, together with Annex IV or V;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

*Status: Point in time view as at 01/04/2004. This version of this provision has been superseded.*

*Changes to legislation: The Medical Devices Regulations 2002, Section 13 is up to date with all changes known to be in force on or before 06 August 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. (See end of Document for details)*

[<sup>F1</sup>(5) Notwithstanding that the requirement in paragraph (1) to (4) is satisfied, subject to paragraph (6), where a relevant device is manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue its manufacturer or his authorised representative must—

- (a) carry out the risk analysis and risk management procedures set out in the Annex to Directive 2003/32; and
- (b) fulfil his obligations under those procedures

before the device may bear a CE marking.

(6) Paragraph (5) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.]

#### **Textual Amendments**

- F1** [Reg. 13\(5\)\(6\)](#) added (1.4.2004) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(b), **6**

**Status:**

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