STATUTORY INSTRUMENTS

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.

[F1(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**