STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Procedures for affixing a CE marking to *in vitro* diagnostic medical devices

40.—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Sections 1 to 6 of Annex III,

(ii) Annex IV, or

(iii) Annex V and either Annex VI or Annex VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV, or

(ii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV,

(ii) Annexes V and VI, or

(iii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.