
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Procedures for affixing a CE marking to active implantable medical devices

27. A relevant device may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
 - (i) Annex 2, or
 - (ii) Annex 3, together with Annex 4 or 5;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 90/385 that apply to it; and
- (c) ensures that the device meets the provisions of Directive 90/385 which apply to it.