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STATUTORY INSTRUMENTS

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**2002 No. 618**

The Medical Devices Regulations 2002

PART II

*General Medical Devices*

**CE marking of general medical devices that come within the scope of more than one Directive**

**11.** Where a relevant device comes within the scope of Directive 93/42 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

- (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;
- (b) the manufacturer chooses to follow the set of arrangements in Directive 93/42;
- (c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and
- (d) the particulars of Directive 93/42, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device.