
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART I

Introductory Provisions Relating to all Medical Devices

Transitional provisions

4.—(1) Part II shall not be applied before 1st July 2004 in respect of a device which has been subjected to EEC pattern approval before 1st January 1995 in accordance with the Clinical Thermometers (EEC Requirements) Regulations 1993⁽¹⁾.

(2) Part II shall not be applied—

- (a) before 10th January 2007 in respect of a stable derivatives device placed on the market without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002; or
- (b) before 10th January 2009 in respect of a stable derivatives device put into service without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002.

(3) Part IV shall not be applied before 7th December 2003 in respect of a device placed on the market which is—

- (a) an *in vitro* diagnostic medical device without a CE marking; or
- (b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 7th December 1998.

(4) Part IV shall not be applied before 7th December 2005 in respect of a device put into service which is—

- (a) an *in vitro* diagnostic medical device without a CE marking; or
- (b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 7th December 1998.