

## STATUTORY INSTRUMENTS

# 2012 No. 1426

## The Medical Devices (Amendment) Regulations 2012

### Amendment of the Medical Devices Regulations 2002

2. Regulation 2 (interpretation) of the Medical Devices Regulations 2002 is amended as follows:

(a) in paragraph (1),

(i) for the definition of “Directive 90/385”, substitute—

““Directive 90/385” means Council Directive [90/385/EEC](#) of 20 June 1990 on the approximation of the laws of Member States relating to active implantable devices <sup>M1</sup>”.

(ii) For the definition of “Directive 93/42”, substitute—

““Directive 93/42” means Council Directive [93/42/EEC](#) of 14 June 1993 concerning medical devices <sup>M2</sup>”.

(iii) For the definition of “Directive 98/79”, substitute—

““Directive 98/79” means Directive [98/79/EC](#) of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices <sup>M3</sup>”.

(b) after paragraph (1), insert—

“(1A) In these Regulations, any reference to Annexes 1 to 7 to Directive 90/385, Annexes I to X to Directive 93/42 or Annex I to X to Directive 98/79 is to be construed as a reference to those Annexes as amended from time to time.”.

#### Marginal Citations

**M1** Directive 90/385/EEC as amended by Council Directive 93/43/EEC (OJ No.L.169, 12/7/1993, p.1), Council Directive 93/68/EEC (OJ No.L.220, 30.8.1993, p.1), Regulation (EC) No.1882/2003 (OJ No. L284, 31.10.2003, p.1) and Directive 2007/47/EC (OJ No. 1.247, 21.9.2007, p.21).

**M2** Directive 93/42/EEC was amended by Directive 98/79/EC (OJ No. L.331, 7.12.1998, p.1), Directive 2000/70/EC (OJ No. L.313, 13.12.2000, p.22), Directive 2001/104/EU (OJ No. L.6, 10.1.2002, p.50) and Directive 2007/47/EC (OJ No. L.247, 21.9.2007, p.21).

**M3** Directive 98/79/EC was amended by Regulation (EC) No 1882/2003 (OJ No. L.284, 31.10.2003, p.1), Regulation (EC) No. 596/2009 (OJ No. L.188, 18.7.2009, p.14) and Directive 2011/100 (OJ No. L.341, 22.12.2011, p.50) and was corrected by Corrigendum (OJ No. L.22, 29.1.1999, p.75) and Corrigendum (OJ No. L.6, 10.1.2002, p.70).

**Changes to legislation:**

There are currently no known outstanding effects for the The Medical Devices (Amendment) Regulations 2012, Section 2.