STATUTORY INSTRUMENTS

2013 No. 2327

The Medical Devices (Amendment) Regulations 2013

Amendment of regulation 2 of the 2002 Regulations

2.—(1) Regulation 2 of the 2002 Regulations (interpretation) is amended as follows.

(2) In paragraph (1) omit the following definitions—

(a) "animal";

(b) "Directive 2003/32";

(c) "EEA State";

(d) "non-viable"; and

(e) "tissue".

(3) In paragraph (1) for the definition of "European Economic Area" substitute—

""European Economic Area" means the European Economic Area created by the EEA Agreement;".

(4) In paragraph (1) in the definition of "the Medical Devices Directives" for "read with Directive 2003/32" substitute "both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012".

(5) In paragraph (1) after the definition of "putting into service" insert the following definitions—

""Regulation (EU) No 207/2012" means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices(**1**);

"Regulation (EU) No 722/2012" means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin(**2**);".

(6) After paragraph (1A) insert the following paragraph—

"(1B) In these Regulations, any reference to Annex 1 to Directive 90/385 or to Annex I to Directive 93/42 is to that Annex read with Regulation (EU) No 207/2012.".

(**1**) OJ No L 72, 10.3.2012, p.28.
(**2**) OJ No L 212, 9.8.2012, p.3.