STATUTORY INSTRUMENTS.

S.I. No. 207 of 2012

EUROPEAN COMMUNITIES (IN VITRO DIAGNOSTIC MEDICAL DEVICES) (AMENDMENT) REGULATIONS, 2012

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EUROPEAN COMMUNITIES (IN VITRO DIAGNOSTIC MEDICAL DEVICES) (AMENDMENT) REGULATIONS, 2012

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (No. 219 of 2011)), for the purpose of giving further effect to Directive 98/79/EC of 27 October 1998 of the European Parliament and of the Council[1], as amended by Commission Directive 2011/100/EU of 20 December 2011[2], hereby make the following regulations:

Citation.

1. These Regulations may be cited as the European Communities (In Vitro Diagnostic Medical Devices) (Amendment) Regulations, 2012.

Collective citation and construction.

2. The European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001 and these Regulations may be cited together as the European Communities (In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2001 and 2012, and shall be construed together as one.

Commencement.

3. These Regulations come into operation on 1st July 2012.

Interpretation.

4. In these Regulations, "Principal Regulations" means the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001).

Amendment of Regulation 2(1) of the Principal Regulations.

5. Regulation 2(1) of the Principal Regulations is amended as follows;

(1) by substituting for the definition of "Annex" of the following definition:

> " 'Annex' means an Annex to Directive 98/79/EC of 27 October 1998[1] as amended by the Annex to Commission Directive 2011/100/EU of 20 December 2011[2];".

[1]OJ No. L331, 7.12.98, p. 1
[2]OJ No. L341, 22.12.2011, p. 50

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 19*th June*, 2012.

(2) by substituting for the definition of "the Directive" of the following definition:

> " 'the Directive' means Directive 98/79/EC of 27 October 1998[1], as amended by Commission Directive 2011/100/EU of 20 December 2011[2];".

L.S.

GIVEN under my Official Seal,
14 June 2012.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Regulations amend the European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001 (S.I. No. 304 of 2001) to give effect to Commission Directive 2011/100/EU of 20 December 2011 (OJ No. L341, 22.12.2011, p.50).

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