STATUTORY INSTRUMENTS.

S.I. No. 547 of 2017

EUROPEAN UNION (MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES) REGULATIONS 2017

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving full effect to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2], hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017.

Definitions

2. In these Regulations—

"Authority" means the Health Products Regulatory Authority;

"Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[1];

"Regulation (EU) 2017/746" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2].

Competent authority

3. (1) The Authority is designated as the competent authority responsible for the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 in the State and shall carry out the functions of the competent authority under those Regulations.

(2) The Authority is appointed as the authority responsible for notified bodies in the State under—

(*a*) Article 35 of Regulation (EU) 2017/745, and

(*b*) Article 31 of Regulation (EU) 2017/746.

(3) In addition to its functions under paragraphs (1) and (2), the Authority shall carry out the functions of the State referred to in—

(*a*) Articles 21(1) and (2), 27(2), 31(5), 33(4), (5) and (7), 59(2), 60, 87(10), 92, 93(8) and 97(2) of Regulation (EU) 2017/745, and

[1]OJ No. L 117, 5.5.2017, p. 1.
[2]OJ No. L 117, 5.5.2017, p. 176.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 8*th December*, 2017.

(*b*) Articles 19(1) and (2), 24(2), 28(5), 30, 54(2), 55, 87, 88(8) and 92(2) of Regulation (EU) 2017/746.

Amendment of Irish Medicines Board Act 1995

4. Section 4(1) of the Irish Medicines Board Act 1995 (No. 29 of 1995) is amended by substituting for paragraph (v) (inserted by section 11(*a*)(v) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) the following paragraphs:

"(v) to exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[1] and carry out the functions conferred on the Authority under Regulation 3(3)(*a*) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

(*w*) to exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2] and carry out the functions conferred on the Authority under Regulation 3(3)(*b*) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

(x) to perform such other functions as are conferred on the Board by this or any other enactment (including any statutory instrument made thereunder).".

Language provisions

5. For the purposes of—

(*a*) Articles 10(11) and (14), 11(3)(*d*), 18(1), 19(1), 41, 52(12), 56 and 89(8) of Regulation (EU) 2017/745, and

(*b*) Articles 10(10) and (13), 11(3)(*d*), 17(1), 37, 48(11), 51 and 88(8) of Regulation (EU) 2017/746,

the language determined by the State is the English language or both the Irish language and the English language.

L.S.

GIVEN under my Official Seal,
4 December 2017.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

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

The purpose of these Regulations is to designate the Health Products Regulatory Authority as the competent authority responsible for enforcing the following EU Regulations:

— Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and

— Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

In addition, these Regulations confer additional powers under those EU Regulations on the Health Products Regulatory Authority and determine the language(*s*) to be used in the State under certain provisions in those EU Regulations.

These Regulations may be cited as the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017.

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