STATUTORY INSTRUMENTS.

S.I. No. 691 of 2021

MEDICAL DEVICES (REGISTRATION) REGULATIONS 2021

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I, STEPHEN DONNELLY, 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), hereby make the following regulations:

Citation

1. These Regulations may be cited as the Medical Devices (Registration) Regulations 2021.

Definitions

2. (1) In these Regulations—

"Active Implantable Medical Devices Directive" means Council Directive 90/385/EEC of 20 June 1990[1], as amended by the Medical Devices Directive, Council Directive 93/68/EEC of 22 July 1993[2], Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003[3] and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007[4];

"Authority" means the Health Products Regulatory Authority;

"device" means—

(*a*) a medical device,

(*b*) an accessory for a medical device,

(*c*) a product listed in Annex XVI to the Medical Devices Regulation, provided the Medical Devices Regulation applies to such product pursuant to Article 1(2) thereof,

(*d*) an *in vitro* diagnostic medical device, or

(*e*) an accessory for an *in vitro* diagnostic medical device, as defined in Article 2(4) of the IVD Medical Devices Regulation,

but does not include—

(i) a product or other substance excluded from the scope of the Medical Devices Regulation by Article 1(6)(b) to (i) thereof,

[1] OJ No. L 189, 20.7.1990, p. 17.
[2] OJ No. L 220, 30.8.1993, p. 1.
[3] OJ No. L 284, 31.10.2003, p. 1.
[4] OJ No. L 247, 21.9.2007, p. 21.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 17*th December,* 2021.

(ii) a product or other substance excluded from the scope of the IVD Medical Devices Regulation by Article 1(3) thereof,

(iii) a device referred to in the second subparagraph of Article 1(8), (9) or (10) of the Medical Devices Regulation, or

(iv) an in-house device.

"*in vitro* diagnostic medical device" has the meaning assigned to it by Article 2(2) of the IVD Medical Devices Regulation;

"in-house device" means a device which—

(*a*) is manufactured and used only within a health institution,

(*b*) complies with all of the conditions in Article 5(5) of the Medical Devices Regulation, and

(*c*) is not manufactured on an industrial scale;

"IVD Medical Devices Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[5];

"manufacturing facility" means a place where an entity which does not place devices on the market under its own name or under its own trademark—

(*a*) manufactures a device,

(*b*) manufactures one or more critical components of a device to a set of specifications,

(*c*) carries out packaging activities in relation to a device, or

(*d*) carries out labelling activities in relation to a device;

"medical device" has the meaning—

(*a*) assigned to it by Article 2(1) of the Medical Devices Regulation,

(*b*) assigned to it by Article 2(2) of IVD Medical Devices Regulation,

(*c*) assigned to the term "device" by Regulation 2(1) of the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994), or

(*d*) assigned to the term "device" by Regulation 2(1) of the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. No. 253 of 1994),

as applicable;

"Medical Devices Directive" means Council Directive 93/42/EEC of 14 June 1993[6], as amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[7], Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000[8], Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001[9], Regulation (EC)

[5] OJ No. L 117, 5.5.2017, p. 176.
[6] OJ No. L 189, 20.7.1990, p. 17.
[7] OJ No. L 331, 7.12.1998, p. 1.
[8] OJ No. L 313, 13.12.2000, p. 22.
[9] OJ No. L 6, 10.1.2002, p. 50.

No. 1882/2003 of the European Parliament and of the Council of 29 September 2003[3] and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007[4];

"Medical Devices Regulation" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[10], as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020[11].

(2) A word or expression which is used in these Regulations, and which is also used in the Medical Devices Regulation, the IVD Medical Devices Regulation, the Medical Devices Directive, or the Active Implantable Medical Devices Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the said Regulation or Directive, as applicable.

Registration requirements in relation to devices

3. (1) This Regulation applies to devices, other than custom-made devices, placed on the market in the European Economic Area in accordance with—

(*a*) the Medical Devices Regulation,

(*b*) Article 110(5) of the IVD Medical Devices Regulation, or

(*c*) the Medical Devices Directive or the Active Implantable Devices Directive, as applicable, pursuant to Article 120(3) of the Medical Devices Regulation.

(2) A manufacturer who, having his or her established place of business in the State, places a device on the market under his or her own name shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and registered place of business, and

(*b*) supply the Authority with a description of the device which is sufficient to identify it.

(3) A manufacturer who, having designated an authorised representative which has his or her established place of business in the State, places a device on the market shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and registered place of business,

(*b*) supply the Authority with a description of the device which is sufficient to identify it, and

(*c*) furnish the Authority with sufficient evidence to establish that he or she has designated his or her authorised representative in respect of the device concerned in accordance with Article 11 of the Medical Devices Regulation, Article 11 of the IVD Medical Devices Regulation, Article 14(2) of the Medical Devices

[10] OJ No. L 117, 5.5.2017, p. 1.
[11] OJ No. L 130, 24.4.2020, p. 18.

Directive or Article 10a(2) of the Active Implantable Medical Devices Directive, as applicable.

(4) An authorised representative who, having his or her established place of business in the State, places a device on the market shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and registered place of business,

(*b*) supply the Authority with a description of the device which is sufficient to identify it, and

(*c*) furnish the Authority with sufficient evidence to establish that he or she has been designated by the manufacturer as his or her authorised representative in respect of the device concerned in accordance with Article 11 of the Medical Devices Regulation, Article 11 of the IVD Medical Devices Regulation, Article 14(2) of the Medical Devices Directive or Article 10a(2) of the Active Implantable Medical Devices Directive, as applicable.

Additional registration requirements in relation to devices other than IVD devices

4. (1) This Regulation applies to devices, other than custom-made devices, placed on the market in the European Economic Area in accordance with—

(*a*) the Medical Devices Regulation, or

(*b*) the Medical Devices Directive or the Active Implantable Devices Directive, as applicable, pursuant to Article 120(3) of the Medical Devices Regulation.

(2) An importer who, having his or her established place of business in the State, places a device on the market shall, in the manner prescribed

by the Authority—

(*a*) notify the Authority of—

(i) his or her name and registered place of business,

(ii) the name and registered place of business of the manufacturer of the device, and

(iii) the name and registered place of business of the authorised representative designated by the manufacturer of the device, and

(*b*) supply the Authority with information relating to the category of the device.

(3) A distributor who, having his or her established place of business in the State, places a device on the market shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and registered place of business, and

(*b*) supply the Authority with information relating to the category of the device.

Registration requirements in relation to custom-made devices

5. A manufacturer who, having his or her established place of business in the State, places a custom-made device on the market in the European Economic Area, in accordance with Article 52(8) of the Medical Devices Regulation, Article 11(6) of the Medical Devices Directive or Article 9(2) of the Active Implantable Medical Devices Directive, shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and place of business, and

(*b*) supply the Authority with a description of the device which is sufficient to identify it.

Registration requirements in relation to systems and procedure packs

6. Any person who, having his or her established place of business in the State, places a system or procedure pack on the market in the European Economic Area in accordance with Article 22 of the Medical Devices Regulation or Article 12 of the Medical Devices Directive shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of his or her name and registered place of business, and

(*b*) supply the Authority with a description of the system or procedure pack which is sufficient to identify it.

Registration requirements in relation to health institutions

7. A health institution in the State which manufactures and uses an in-house device within that institution shall, in the manner prescribed by the Authority—

(*a*) notify the Authority of its name and address, and

(*b*) supply the Authority with information about the in-house device on request.

Registration requirements in relation to manufacturing facilities

8. A manufacturing facility in the State shall, in the manner prescribed by the Authority—

(*a*) notify the Authority in writing of the name and address of the facility, and

(*b*) supply the Authority with information regarding the activity relating to devices carried out in the facility.

L.S.

GIVEN under my Official Seal,
9 December, 2021.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations are made under section 32 of the Irish Medicines Board Act 1995 and provide for registration requirements in relation to medical devices, and other devices, placed on the market in the State.

These Regulations may be cited as the Medical Devices (Registration) Regulations 2021.

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