STATUTORY INSTRUMENTS.

S.I. No. 365 of 2022

IN VITRO DIAGNOSTIC MEDICAL DEVICES (REGISTRATION) REGULATIONS 2022

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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 *In Vitro* Diagnostic Medical Devices (Registration) Regulations 2022.

Definitions

2. (1) In these Regulations—

"Authority" means the Health Products Regulatory Authority;

"device" means—

(a) an *in vitro* diagnostic medical device,
(b) an accessory for an *in vitro* diagnostic medical device,

and does not include—

(i) a product or other substance excluded by Article 1(3) of the IVD Medical Devices Regulation,
(ii) an in-house device;

"Directive" means Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[1] as amended by Commission Directive 2011/100/EU of 20 December 2011;[2]

"IVD Medical Devices Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[3] as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25

[1] OJ No. L331, 7.12.98, p. 1.
[2] OJ No. L341, 22.12.2011, p. 50.
[3] OJ No. L 117, 5.5.2017, p. 176.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 22*nd July,* 2022.

January 2022;[4]

"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 IVD Medical Devices Regulation, and

(c) is not manufactured on an industrial scale;

"*in vitro* diagnostic medical device" has the meaning —

(a) assigned to it by Article 2(2) of the IVD Medical Devices Regulation, or

(b) assigned to the term "*in vitro* diagnostic medical device" by Regulation 2(1) of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001),

as applicable;

"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;

(2) A word or expression which is used in these Regulations, and which is also used in the IVD Medical Devices Regulation or the 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 placed on the market in the European Economic Area in accordance with —

(a) the IVD Medical Devices Regulation, and

[4] OJ No. L 19, 28.1.2022, p. 3.

(b) the Directive pursuant to Article 110(3) of the IVD 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 IVD Medical Devices Regulation or Article 10(3) of the Directive, as applicable.

(4) An authorised representative having his or her established place of business in the State, 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 IVD Medical Devices Regulation or Article 10(3) of the Directive, as applicable.

(5) 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

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

(6) A distributor who, having his or her established place of business in the State, makes a device available 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 health institutions

4. 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

5. 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,
14 July, 2022.

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.

The purpose of these Regulations is to provide for registration requirements in relation to *in vitro* diagnostic medical devices placed on the market in the State.

These Regulations may be cited as the *In Vitro* Diagnostic Medical Devices (Registration) Regulations 2022.

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