STATUTORY INSTRUMENTS.

S.I. No. 301 of 2020

EUROPEAN COMMUNITIES (MEDICAL DEVICES) (AMENDMENT) (NO. 2) REGULATIONS 2020

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I, Stephen Donnelly, 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 further effect to Council Directive 93/42/EEC of 14 June 1993[1], as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007[2], and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[3], as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020[4], hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Medical Devices) (Amendment) (No. 2) Regulations 2020.

(2) The collective citation "the European Communities (Medical Devices) Regulations 1994 to 2020" includes these Regulations.

2. In these Regulations, "Principal Regulations" means the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994).

3. Article 12 (as amended by Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2020 (S.I. No. 144 of 2020)) of the Principal Regulations is amended—

(*a*) in subarticle (10), by substituting "public health or patient safety or health" for "protection of health", and

(*b*) in subarticle (10A), by substituting "public health or patient safety or health" for "protection of public health".

4. The Principal Regulations are amended by inserting after Article 27 the following Article:

"*Information on incidents occurring following placing of devices on market*

28. (1) The Competent Authority shall record and evaluate any information brought to its attention, in accordance with the provisions of the Directive or these Regulations, regarding the following incidents involving a Class I, IIa, IIb or III device:

[1] OJ No. L 169, 12.7.1993, p. 1.
[2] OJ No. L 247, 21.9.2007, p. 21.
[3] OJ No. L 117, 5.5.2017, p. 1.
[4] OJ No. L 130, 24.4.2020, p. 18.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 14*th August,* 2020.

(*a*) any malfunction or deterioration in the characteristics or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his or her state of health; and

(*b*) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in paragraph (a), leading to systematic recall of devices of the same type by the manufacturer.

(2) After carrying out an assessment, if possible together with the manufacturer or his or her authorised representative, the Competent Authority shall, without prejudice to Article 19(A), immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise recurrence of the incidents referred to in subarticle (1), including information on the underlying incidents.".

L.S.

GIVEN under my Official Seal,
6 August, 2020.

STEPHEN DONNELLY,
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 give effect to Regulation 59(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020. In addition, these Regulations implement Article 10 of Council Directive 93/42/EEC of 14 June 1993 in the State.

These Regulations amend the European Communities (Medical Devices) Regulations 1994.

These Regulations may be cited as the European Communities (Medical Devices) (Amendment) (No. 2) Regulations 2020.

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