STATUTORY INSTRUMENTS.

S.I. No. 302 of 2020

EUROPEAN COMMUNITIES (IN VITRO DIAGNOSTIC 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 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[1], hereby make the following regulations:

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

(2) The collective citation "the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 1998 to 2020" includes these Regulations.

2. The European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001) are amended by inserting after Regulation 22 the following Regulation:

"*Vigilance procedure*

23. (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 devices bearing the CE marking:

(*a*) any malfunction, failure or deterioration in the characteristics or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their 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 subparagraph (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 Regulation 14, immediately inform the Commission and the other Member States of the incidents referred to in paragraph (1) for which appropriate measures, including possible withdrawal, have been taken or are contemplated.".

[1] OJ No. L 331, 7.12.1998, p. 1.

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

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 fully implement Article 11 of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 in the State.

These Regulations amend the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 2001.

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

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