S.I. No. 300 of 2020

EUROPEAN COMMUNITIES (ACTIVE IMPLANTABLE MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2020

1. (1) These Regulations may be cited as the European Communities (Active Implantable Medical Devices) (Amendment) Regulations 2020.

(2) The Principal Regulations, Regulations 2(3) and 20 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), the Regulations of 2009 and these Regulations may be cited together as the European Communities (Active Implantable Medical Devices) Regulations 1994 to 2020 and shall be construed together as one.

2. In these Regulations—

“Principal Regulations” means the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. No. 253 of 1994);


3. Article 7(5) of the Principal Regulations is amended by substituting “public health or patient safety or health” for “protection of health”.

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\(^1\) OJ No. L 189, 20.7.1990, p. 17.
\(^3\) OJ No. L 130, 24.4.2020, p. 18.
4. The Principal Regulations are amended by inserting after Article 21 the following Article:

“Information on incidents occurring following placing of devices on market

22. (1) The Competent Authority shall record and evaluate any information brought to its attention regarding the following incidents involving a device:

(a) any malfunction of or deterioration in the characteristics and performances of a device, as well as any inadequacy in the labelling or in 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 performances 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 13(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.”.

GIVEN under my Official Seal,

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 amend the European Communities (Active Implantable Medical Devices) Regulations 1994.

These Regulations may be cited as the European Communities (Active Implantable Medical Devices) (Amendment) Regulations 2020.