



STATUTORY INSTRUMENTS.

S.I. No. 144 of 2020



EUROPEAN COMMUNITIES (MEDICAL DEVICES) (AMENDMENT)
REGULATIONS 2020

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I, SIMON HARRIS, 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 1993¹, hereby make the following regulations:

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

(2) The Principal Regulations, the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001) (other than Regulation 20 thereof), the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Regulations of 2009 and these Regulations may be cited together as the European Communities (Medical Devices) Regulations 1994 to 2020 and shall be construed together as one.

2. In these Regulations—

“Principal Regulations” means the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994);

“Regulations of 2009” means the European Communities (Medical Devices) (Amendment) Regulations 2009 (S.I. No. 11 of 2009).

3. Article 12 (as amended by Regulations 21 and 22 of the Regulations of 2009) of the Principal Regulations is amended by inserting after subarticle (10) the following subarticles:

“(10A) Without prejudice to subarticle (10), in the context of the Covid-19 emergency, the Minister may, notwithstanding non-compliance with article 7, 8, 9, 10 or 15, authorise the placing on the market or putting into service of medical devices if he or she is satisfied, having consulted relevant expert bodies, committees or individuals, that such authorisation is in the interest of protection of public health.

(10B) In subarticle (10A), “Covid-19 emergency” means the situation resulting from the spread in the State of the disease caused by infection

¹ OJ No. L 169, 12.7.1993, p. 1.

with the virus SARS-CoV-2, being a disease specified as an infectious disease in accordance with Regulation 6 of, and the Schedule to, the Infectious Diseases Regulations 1981 (S.I. No. 390 of 1981), or any variant of the disease so specified as an infectious disease in those Regulations.

(10C) Where the Minister authorises the placing on the market or putting into service of a medical device under subarticle (10A), he or she shall notify the Competent Authority.”



GIVEN under my Official Seal,
23 April, 2020.

SIMON HARRIS,
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 the Minister for Health the power, in the context of the Covid-19 emergency, to authorise the placing on the market or putting into service of non-CE marked medical devices.

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

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

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