STATUTORY INSTRUMENTS.

S.I. No. 145 of 2020

EUROPEAN COMMUNITIES (IN VITRO DIAGNOSTIC 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 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) Regulations 2020.

(2) The Principal Regulations, the European Communities (*In Vitro* Diagnostic Medical Devices) (Amendment) Regulations 2012 (S.I. No. 207 of 2012) and these Regulations may be cited together as the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 1998 to 2020 and shall be construed together as one.

2. In these Regulations "Principal Regulations" means the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001).

3. Regulation 8 of the Principal Regulations is amended by inserting after paragraph (11) the following paragraphs:

"(11A) Without prejudice to paragraph (11), in the context of the Covid-19 emergency, the Minister may, notwithstanding Regulation 7, authorise the placing on the market or putting into service of 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.

(11B) In paragraph (10A), "Covid-19 emergency" means the situation resulting from the spread in the State of the disease caused by infection 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.

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

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 28*th April,* 2020.

(11C) Where the Minister authorises the placing on the market or putting into service of a device under paragraph (11A), he or she shall notify the competent authority.”.

L.S.

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 in vitro diagnostic medical devices.

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) Regulations 2020.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2,
D02 DR67.

Teil: 076 110 6834
r-post: publications@opw.ie

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