



STATUTORY INSTRUMENTS.

S.I. No. 510 of 2021

MEDICAL DEVICES (AMENDMENT) REGULATIONS 2021

MEDICAL DEVICES (AMENDMENT) REGULATIONS 2021

I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) of the Irish Medicines Board Act 1995 (No. 29 of 1995) and for the purpose of giving further effect to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017¹, hereby make the following regulations:

1. (1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2021.

(2) The Principal Regulations and these Regulations may be cited together as the Medical Devices Regulations 2021.

2. In these Regulations “Principal Regulations” means the Medical Devices Regulations (S.I. No. 261 of 2021).

3. Regulation 3(1) of the Principal Regulations is amended—

- (a) by deleting the definition of “combination product”;
- (b) in the definition of “device”, by substituting “a device referred to in the second subparagraph of Article 1(8), (9) or (10) of the EU Regulation” for “a combination product”,
- (c) by substituting for the definition of “in-house device” the following:

“in-house device’ means a device which—

 - (a) is manufactured and used only within a health institution,
 - (b) complies with all of the conditions in Article 5(5) of the EU Regulation, and
 - (c) is not manufactured on an industrial scale;”,
- (d) by substituting for the definition of “member state” the following:

“member state’ means a member state of the European Economic Area;”,
- (e) in the definition of “premises”, by deleting “medical”,
- (f) in the definition of “record”—
 - (i) by substituting “thing” for “device” in both places it occurs, and

¹ OJ No. L 117, 5.5.2017, p. 1.

- (ii) by substituting “without the aid of” for “without the aid or” in both places it occurs, and
- (g) by substituting for the definition of “relevant thing” the following:

“‘relevant thing’ means—

 - (a) a device,
 - (b) a device referred to in the second subparagraph of Article 1(8), (9) or (10) of the EU Regulation,
 - (c) an in-house device,
 - (d) any article or substance used in the manufacture, processing, packaging, labelling, preparation, storage, distribution or advertising of a device referred to in subparagraph (a), (b) or (c),
 - (e) a system,
 - (f) a procedure pack, or
 - (g) another product being used, or purporting to be used, for a medical purpose;”.

4. Regulation 5 of the Principal Regulations is amended by substituting “under these Regulations, the EU Regulation and the Market Surveillance Regulation” for “under these Regulations and the EU Regulation” in both places it occurs.

5. Regulation 18(m)(iii) of the Principal Regulations is amended by substituting “or the Authority” for “and the competent authority”.

6. Regulation 19(t)(iii) of the Principal Regulations is amended by substituting “the manufacturer” for “a manufacturer”.

7. Regulation 21(p) of the Principal Regulations is amended by substituting “Article 55(1)” for “Article 55(4)”.

8. Regulation 23 of the Principal Regulations is amended—

- (a) in paragraph (1)—
 - (i) in subparagraph (l), by substituting “in accordance with Article 80(1) of the EU Regulation ” for “referred to in Article 80(1) of the EU Regulation in relation to an adverse event”, and
 - (ii) in subparagraph (m), by substituting “in accordance with Article 80(2), (3) or (4) of the EU Regulation, as applicable” for “the information referred to in Article 80(2)

of the EU Regulation in relation to a serious adverse event, in accordance with that provision or Article 80(3) or (4) of the EU Regulation, as applicable”, and

- (b) in paragraph (4), by substituting “Article 65(a) or (b) of the EU Regulation” for “Article 65(1)(a) or (b) of the EU Regulation”.

9. Regulation 24 of the Principal Regulations is amended—

- (a) in paragraph (b), by substituting “device referred to in the second subparagraph of Article 1(8), (9) or (10) of the EU Regulation,” for “combination product”,
- (b) in paragraph (z), by substituting “these Regulations” for “this Regulation”,
- (c) by substituting for paragraph (bb) the following:
“(bb) tampers with any device or other relevant thing, or any material or accessory designated to be used as part of or with a device or other relevant thing,”, and
- (d) in paragraph (cc), by substituting “Regulation 28(3)(i) or (j)” for Regulation 29(3)(i) or (j).

10. The Principal Regulations are amended by substituting the heading “PART 5 COMPLIANCE AND ENFORCEMENT” for the heading “PART 4 COMPLIANCE AND ENFORCEMENT”.

11. Regulation 28(3) of the Principal Regulations is amended—

- (a) in subparagraph (l), by substituting “inspect” for “search”, and
- (b) in subparagraph (r)(i), by substituting “and other relevant things” for “and related products”.

12. Regulation 31 of the Principal Regulations is amended—

- (a) in paragraph (1)—
 - (i) by inserting “or these Regulations” after “the EU Regulation”, and
 - (ii) by inserting “other” after “device or” in both places it occurs, and
- (b) in paragraph (2)(c)(i), by inserting “or these Regulations” after “the EU Regulation”.

13. Regulation 32 of the Principal Regulations is amended—

- (a) in paragraph (1), by inserting “or these Regulations” after “the EU Regulation”,
- (b) in paragraph (2)—
 - (i) in subparagraph (b), by inserting “or these Regulations” after “the EU Regulation”, and
 - (ii) in subparagraph (d), by inserting “, the health institution of the in-house device concerned, or the person responsible for the relevant thing concerned” after “device concerned”, and
- (c) in paragraph (3), by inserting “, the person responsible in the health institution in respect of the in-house device concerned, or the person responsible for the relevant thing concerned,” after “device concerned”.

14. Regulation 33 of the Principal Regulations is amended—

- (a) in paragraph (1),
 - (i) in subparagraph (a), by inserting “or these Regulations” after “EU Regulation”, and
 - (ii) in subparagraph (b), by inserting “or other relevant thing” after “a device”,
- (b) in paragraph (2),
 - (i) by inserting “or these Regulations” after “the EU Regulation” in each place it occurs,
 - (ii) in subparagraph (b), by inserting “or relevant thing” after “device concerned”,
 - (iii) in subparagraph (c), by inserting “, or relevant thing,” after “the device”, and
 - (iv) in subparagraph (e), by inserting “, or relevant thing,” after “the device” in each place it occurs,
- (c) in paragraph (4), by inserting “, the person responsible in the health institution in respect of the in-house device concerned, or the person responsible for the relevant thing concerned,” after “the device concerned”, and
- (d) in paragraph (7), by inserting “or relevant things” after “devices”.

15. Regulation 38(1)(f) of the Principal Regulations is amended by deleting “device or”.

16. The Principal Regulations are amended by substituting the heading “PART 6 REVOCATIONS AND TRANSITIONAL PROVISIONS” for the heading “PART 5 REVOCATIONS AND TRANSITIONAL PROVISIONS”.

17. Regulation 39(d) of the Principal Regulations is amended by substituting “Regulations 3 and 12” for “Regulation 3”.

18. Regulation 40 of the Principal Regulations is amended—

- (a) in paragraph (3)(ii), by substituting “the Eudamed functionality date” for “Eudamed is functional”, and
- (b) in paragraph (10), by substituting “Article 34(3)” for “Article 24(3)”.



GIVEN under my Official Seal,
7 October, 2021.

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 Medical Devices Regulations 2021 to exclude Switzerland from the definition of “member state” and make various other minor changes.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach 6
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Tel: 046 942 3100
r-phost: publications@opw.ie

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
MOUNTSHANNON ROAD,
KILMAINHAM, DUBLIN 8,
D08 XAO6

Tel: 046 942 3100
E-mail: publications@opw.ie

€3.00

ISBN 978-1-3993-1128-1



9 781399 311281