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LEGISLATIVE ACTS AND OTHER INSTRUMENTS: CORRIGENDUM/RECTIFICATIF

Subject:	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *(Official Journal of the European Union L 117 of 5 May 2017)*

LANGUAGES concerned: **All linguistic versions**

PROCEDURE APPLICABLE (according to Council document R/2521/75):

— Procedure 2(c) (obvious errors in all language versions)

This text has also been transmitted to the European Parliament.

TIME LIMIT for the observations by Member States: 8 days

OBSERVATIONS to be notified to: dql.rectificatifs@consilium.europa.eu

(DQL RECTIFICATIFS (JUR 7), Directorate Quality of Legislation, Legal Service)

ANNEX

CORRIGENDUM

to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Official Journal of the European Union L 117 of 5 May 2017)

On page 69, point (c) of the second subparagraph of Article 78(8)

for:

'(c) considerations as regards subject safety and data reliability and robustness submitted under point (b) of paragraph 4.',

read:

'(c) considerations as regards subject safety and data reliability and robustness submitted under point (d) of paragraph 4.'.

On page 72, Article 84, first sentence

for:

'Section 1.1 of Annex III',

read:

'Section 1 of Annex III'.

On page 74, the first subparagraph of Article 88(1)

for:

'… referred to in Sections 1 and 5 of Annex I and which …',

read:

'… referred to in Sections 1 and 8 of Annex I and which …'.

On page 89, Article 120(3)

for:

'3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues …',

read:

'3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues …'.

On page 89, Article 120(4)

for:

'… on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.',

read:

'… on the market from 26 May 2020 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.'.

On page 90, Article 120(8)

for:

'8. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to point (d) of Article 123(3) and ending 18 months later, comply with Article 29(4) and Article 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Decision 2010/227/EU.',

read:

'8. By way of derogation from Article 10a, point (a) of Article 10b(1) and Article 11(5) of Directive 90/385/EEC and Article 14(1) and (2), points (a) and (b) of Article 14a(1) and Article 16(5) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (d) of Article 123(3) and ending 18 months later, comply with Articles 29(4), 31(1) and 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC, with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC and with, respectively, Article 11(5) of Directive 90/385/EEC or Article 16(5) of Directive 93/42/EEC, as specified in Decision 2010/227/EU.'.

On page 90, Article 122, first paragraph, second indent

for:

'– Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC, and …',

read:

'– Article 10a, point (a) of Article 10b(1) and Article 11(5) of Directive 90/385/EEC, and …'.

On page 91, Article 122, first paragraph, fourth indent

for:

'– Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, and …';

read:

'– Article 14(1) and (2), points (a) and (b) of Article 14a(1) and Article 16(5) of Directive 93/42/EEC, and …'.

On page 104, Annex I, Section 23.2, point (h)

for:

'(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;',

read:

'(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VI;'.

On page 112, Annex III, Section 1.1

for:

'1.1. The post-market …',

read:

'1. The post-market …'.

On page 112, Annex III, Section 1.1, point (b), fifth bullet point

for:

'– methods and protocols to manage the events subject to the trend report …',

read:

'– methods and protocols to manage the incidents subject to the trend report …'.

On page 112, Annex III, Section 1.2

for:

'1.2. The PSUR …',

read:

'2. The PSUR …'.