

**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)*

1. On page 17, point 30 of Article 2:

*for:* '(30) "manufacturer" means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;'

*read:* '(30) "manufacturer" means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark;'

2. On page 22, Article 7, introductory phrase:

*for:* 'In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and ...'

*read:* 'In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and ...'

3. On page 25, Article 10(15):

*for:* '15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).'

*read:* '15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4).'

4. On page 66, Article 74(1):

*for:* '... of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions ...'

*read:* '... of Article 62(4), Articles 75, 76 and 77, and Article 80(5) and (6), and the relevant provisions ...'

5. On page 69, Article 78(14):

*for:* '14. The procedure set out in this Article shall, until 27 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.'

*read:* '14. The procedure set out in this Article shall, until 25 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. From 26 May 2027, all Member States shall be required to apply that procedure.'

6. On page 89, Article 120(6), second line:

*for:* '... and notified prior 26 May 2020. Notified bodies ...'

*read:* '... and notified prior to 26 May 2020. Notified bodies ...'

7. On page 90, Article 120(10):

*for:* 'Devices falling within the scope of this Regulation in accordance with points (f) and (g) of Article 1(6) which ...'

*read:* 'Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which ...'

8. On page 132, Annex VII, Section 4.5.2, point (a), fourth indent:

*for:* '...That plan shall ensure that all devices covered by the certificate are sampled over ...',

*read:* '...That plan shall ensure that the entire range of devices covered by the certificate is sampled over ...'.

9. On page 140, Annex VIII, Section 3.2:

*for:* '... Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right ...',

*read:* '... Accessories for a medical device shall be classified in their own right ...'.

10. On page 148, Annex IX, Section 2.3, third paragraph, first sentence:

*for:* 'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing ...',

*read:* 'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis as specified in Section 4. In choosing ...'.

11. On page 148, Annex IX, Section 3:

*for:* '3. Surveillance assessment applicable to class IIa, class IIb and class III devices',

*read:* '3. Surveillance assessment'.

12. On page 149, Annex IX, Section 3.5, first paragraph:

*for:* 'In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.',

*read:* 'In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.'.

13. On page 149, Annex IX, Section 4.3:

*for:* 'The notified body shall examine the application by using staff, employed by it, with proven knowledge ...',

*read:* 'The notified body shall assess the technical documentation using staff with proven knowledge ...'.

14. On page 169, Annex XV, Chapter II, Section 2.5:

*for:* '2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.',

*read:* '2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable side-effects, contraindications and warnings.'.

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