

Corrigendum to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

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

1. On page 183, Recital (66)

for: '(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of performance studies ...',

read: '(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 20916 on clinical performance studies using specimens from human subjects, currently under development, so as to make it easier for the results of performance studies ...'.

2. On page 198, Article 10(14)

for: '14. 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 27(1).',

read: '14. 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 26(3).',

3. On page 207, Article 28(1)

for: '... in Article 30 the information ...',

read: '... in Article 27 the information ...'.

4. On page 220, Article 48(7), first subparagraph

for: '... of Annex IX, including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex of at least one ...',

read: '... of Annex IX, and, in addition, to an assessment of the technical documentation as specified in Section 4 of that Annex for at least one ...'.

5. On page 221, Article 48(9), first subparagraph:

for: '... of Annex IX, and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative ...',

read: '... of Annex IX, and, in addition, to an assessment of the technical documentation as specified in Section 4 of that Annex for at least one representative ...'.

6. On page 234, Article 70(1)

for: '... of Article 58(5), and Articles 71, 72 and 73 Article 76(5) and the relevant provisions ...',

read: '... of Article 58(5), Articles 71, 72 and 73, and Article 76(5) and (6), and the relevant provisions ...'.

7. On page 238, Article 74(14)

for: '14. The procedure set out in this Article shall, until 27 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. After 27 May 2029, all Member States shall be required to apply that procedure.',

read: ‘14. The procedure set out in this Article shall, until 25 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. From 26 May 2029, all Member States shall be required to apply that procedure.’.

8. On page 256, Article 110(4)

for: ‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market 26 May 2022 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: ‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market from 26 May 2022 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.’.

9. On page 258, point (g) of Article 113(3)

for: ‘(g) The procedure set out in Article 74 shall, apply from 26 May 2027 without prejudice to Article 74(14).’,

read: ‘(g) the procedure set out in Article 74 shall apply from 26 May 2029 without prejudice to Article 74(14).’.

10. On page 296, 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 the period of validity of the certificate.’,

read: ‘That plan shall ensure that the entire range of devices covered by the certificate is sampled over the period of validity of the certificate, and’.

11. On page 306, Annex IX, Section 2.1, sixth indent

for: ‘... procedures in place to fulfil the obligations arising from by the quality management system ...’,

read: ‘... procedures in place to fulfil the obligations arising from the quality management system ...’.

12. On page 308, Annex IX, Section 2.3, first subparagraph

for: ‘... unless it duly substantiate not doing so.’,

read: ‘... unless it duly substantiates not doing so.’.

13. On page 308, Annex IX, Section 2.3, third subparagraph

for: ‘Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing ...’,

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

14. On page 308, Annex IX, Section 2.3, fourth subparagraph, second sentence

for: ‘The notified body shall notify the manufacturer of its decision to issue the certificate.’,

read: ‘The notified body shall notify the manufacturer of its decision to issue the certificate.’.

15. On page 308, Annex IX, Section 3

for: ‘3. Surveillance assessment applicable to class C and class D devices’,

read: ‘3. Surveillance assessment’.

16. On page 309, Annex IX, Section 3.5

for: 'In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative ...',

read: 'In the case of class B and C 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 ...'.

17. On page 310, 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 ...'.



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