

## DECISION OF THE EEA JOINT COMMITTEE

No 301/2019

of 13 December 2019

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2020/319]

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) 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 <sup>(1)</sup>, as corrected by OJ L 117, 3.5.2019, p. 11, is to be incorporated into the EEA Agreement.
- (2) Regulation (EU) 2017/746 repeals Directive 98/79/EC <sup>(2)</sup> and Commission Decision 2010/227/EU <sup>(3)</sup>, which are incorporated into the EEA Agreement and which are consequently to be repealed under the EEA Agreement with effect from the dates referred to in Article 112 of Regulation (EU) 2017/746.
- (3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1*

Chapter XXX of Annex II to the EEA Agreement shall be amended as follows:

1. The following is inserted after point 11 (Regulation (EU) 2017/745 of the European Parliament and of the Council):  
  
‘12. **32017 R 0746**: 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 (OJ L 117, 5.5.2017, p. 176), as corrected by OJ L 117, 3.5.2019, p. 11.’
2. The texts of points 2 (Directive 98/79/EC of the European Parliament and of the Council) and 8 (Commission Decision 2010/227/EU) are deleted with effect from the dates referred to in Article 112 of Regulation (EU) 2017/746.

*Article 2*

The text of Regulation (EU) 2017/746, as corrected by OJ L 117, 3.5.2019, p. 11, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

<sup>(1)</sup> OJ L 117, 5.5.2017, p. 176.

<sup>(2)</sup> OJ L 331, 7.12.1998, p. 1.

<sup>(3)</sup> OJ L 102, 23.4.2010, p. 45.

*Article 3*

This Decision shall enter into force on 14 December 2019, or on the day following the last notification to the EEA Joint Committee under Article 103(1) of the EEA Agreement have been made (\*), or on the day of the entry into force of Decision of the EEA Joint Committee No 288/2019 of 13 December 2019 (†), whichever is the later.

*Article 4*

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 13 December 2019.

*For the EEA Joint Committee*

*The President*

Gunnar PÁLSSON

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(\*) Constitutional requirements indicated.

(†) See page 24 of this Official Journal.