

DECISION OF THE EEA JOINT COMMITTEE

No 164/2012

of 28 September 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

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) Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Decision 2009/886/EC of 27 November 2009 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices ⁽²⁾, as corrected by OJ L 348, 29.12.2009, p. 94, is to be incorporated into the EEA Agreement.
- (3) Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Decision 2009/886/EC repeals Commission Decision 2009/108/EC ⁽⁴⁾ which is incorporated into the Agreement and which is consequently to be repealed under the EEA Agreement.
- (5) 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 shall be added in point 2 (Directive 98/79/EC of the European Parliament and of the Council):

, as amended by:

- **32011 L 0100**: Commission Directive 2011/100/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 50).;
- (2) the first indent in point 3 (Commission Decision 2002/364/EC) shall be deleted;
- (3) the following indents shall be added in point 3 (Commission Decision 2002/364/EC):
 - **32009 D 0886**: Commission Decision 2009/886/EC of 27 November 2009 (OJ L 318, 4.12.2009, p. 25), as corrected by OJ L 348, 29.12.2009, p. 94,
 - **32011 D 0869**: Commission Decision 2011/869/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 63).

Article 2

The texts of Directive 2011/100/EU, Decision 2009/886/EC, as corrected by OJ L 348, 29.12.2009, p. 94, and Decision 2011/869/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

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, 28 September 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 341, 22.12.2011, p. 50.⁽²⁾ OJ L 318, 4.12.2009, p. 25.⁽³⁾ OJ L 341, 22.12.2012, p. 63.⁽⁴⁾ OJ L 39, 10.2.2009, p. 34.

(*) No constitutional requirements indicated.