

DECISION OF THE EEA JOINT COMMITTEE

No 198/2012

of 26 October 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 Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following point shall be inserted after point 8 (Commission Decision 2010/227/EU) of Chapter XXX of Annex II to the EEA Agreement:

'9. **32012 R 0207**: Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).'

Article 2

The text of Regulation (EU) No 207/2012 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, 26 October 2012.

For the EEA Joint Committee
The President
Atle LEIKVOLL

⁽¹⁾ OJ L 72, 10.3.2012, p. 28.

(*) No constitutional requirements indicated.