

DECISION OF THE EEA JOINT COMMITTEE**No 218/2015****of 25 September 2015****amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2017/525]**

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 Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Recommendation 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices ⁽²⁾ is to be incorporated into the EEA Agreement.
- (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 point is inserted after point 9 (Commission Regulation (EU) No 207/2012):
'10. **32013 R 0920**: Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).'
2. The following point is inserted after point 1 (Commission Recommendation 2013/172/EU) under the heading 'ACTS OF WHICH THE CONTRACTING PARTIES SHALL TAKE NOTE':
'2. **32013 H 0473**: Commission Recommendation 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (OJ L 253, 25.9.2013, p. 27).'

*Article 2*The texts of Implementing Regulation (EU) No 920/2013 and Recommendation 2013/473/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 26 September 2015, provided that all the notifications under Article 103(1) of the EEA Agreement have been made ^(*).⁽¹⁾ OJ L 253, 25.9.2013, p. 8.⁽²⁾ OJ L 253, 25.9.2013, p. 27.^(*) No constitutional requirements indicated.

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, 25 September 2015.

For the EEA Joint Committee
The President
Ingrid SCHULERUD
