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**DECISION OF THE EEA JOINT COMMITTEE**  
**No 125/2009**

**of 4 December 2009**

**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, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as ‘the Agreement’, and in particular Article 98 thereof,

Whereas:

- (1) Annex II to the Agreement was amended by Decision of the EEA Joint Committee No 28/2009 of 17 March 2009<sup>1</sup>.
- (2) Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market<sup>2</sup> is to be incorporated into the Agreement.
- (3) Council Directive 93/42/EEC<sup>3</sup> has been incorporated into Chapter IX and Chapter XXX of Annex II to the Agreement. As the Directive concerns medical devices, it should only be referred to in Chapter XXX. The reference to the Directive in Chapter IX is therefore to be deleted.
- (4) Council Directive 90/385/EEC<sup>4</sup> concerns active implantable medical devices and the reference to this Directive should therefore be moved from Chapter X to Chapter XXX of Annex II to the Agreement.

HAS DECIDED AS FOLLOWS:

*Article 1*

Annex II to the Agreement shall be amended as follows:

1. The text of point 27a (Council Directive 93/42/EEC) of Chapter IX shall be deleted.

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<sup>1</sup> OJ L 130, 28.5.2009, p. 21.

<sup>2</sup> OJ L 247, 21.9.2007, p. 21.

<sup>3</sup> OJ L 169, 12.7.1993, p. 1.

<sup>4</sup> OJ L 189, 20.7.1990, p. 17.

2. The text of point 7 (Council Directive 90/385/EEC) of Chapter X shall be deleted.
3. The following indent shall be added in point 12n (Directive 98/8/EC of the European Parliament and of the Council) of Chapter XV and in point 1 (Council Directive 93/42/EEC) of Chapter XXX:
  - ‘- **32007 L 0047**: Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).’
4. The following shall be inserted after point 6 (Commission Directive 2005/50/EC) of Chapter XXX:
  - ‘7. **390 L 0385**: Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), as amended by:
    - **393 L 0042**: Council Directive 93/42/EEC of 14 June 1993 (OJ L 169, 12.7.1993, p. 1),
    - **393 L 0068**: Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1),
    - **32007 L 0047**: Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).

The transitional arrangements set out in the Annexes to the Act of Accession of 16 April 2003 for Poland (Annex XII, Chapter 1, Point 1), shall apply.’

#### *Article 2*

The texts of Directive 2007/47/EC 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 5 December 2009, provided that all the notifications under Article 103(1) of the 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*.

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\* No constitutional requirements indicated.

Done at Brussels, 4 December 2009.

*For the EEA Joint Committee  
The President*

*O. H. Sletnes*

*The Secretaries  
to the EEA Joint Committee*

*B. Ellertsdóttir      L-O. Hollner*