

DECISION OF THE EEA JOINT COMMITTEE**No 122/2014****of 27 June 2014****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 Delegated Directive 2014/1/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Delegated Directive 2014/2/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020 ⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) Commission Delegated Directive 2014/3/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead acetate marker for use in stereotactic head frames for use with CT (Computed Tomography) and MRI and in positioning systems for gamma beam and particle therapy equipment ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Commission Delegated Directive 2014/4/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (5) Commission Delegated Directive 2014/5/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards, termination coatings of electrical and electronic components and coatings of printed circuit boards, solders for connecting wires and cables, solders connecting transducers and sensors that are used durably at a temperature below – 20 °C under normal operating and storage conditions ⁽⁵⁾ is to be incorporated into the EEA Agreement.
- (6) Commission Delegated Directive 2014/6/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below – 20 °C under normal operating and storage conditions ⁽⁶⁾ is to be incorporated into the EEA Agreement.
- (7) Commission Delegated Directive 2014/7/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used (a) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging

⁽¹⁾ OJ L 4, 9.1.2014, p. 45.

⁽²⁾ OJ L 4, 9.1.2014, p. 47.

⁽³⁾ OJ L 4, 9.1.2014, p. 49.

⁽⁴⁾ OJ L 4, 9.1.2014, p. 51.

⁽⁵⁾ OJ L 4, 9.1.2014, p. 53.

⁽⁶⁾ OJ L 4, 9.1.2014, p. 55.

equipment, including patient monitors designed to be used within this sphere, or (b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy ⁽¹⁾ is to be incorporated into the EEA Agreement.

- (8) Commission Delegated Directive 2014/8/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards ⁽²⁾ is to be incorporated into the EEA Agreement.
- (9) Commission Delegated Directive 2014/9/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors ⁽³⁾ is to be incorporated into the EEA Agreement.
- (10) Commission Delegated Directive 2014/10/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (11) Commission Delegated Directive 2014/11/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020 ⁽⁵⁾ is to be incorporated into the EEA Agreement.
- (12) Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment ⁽⁶⁾ is to be incorporated into the EEA Agreement.
- (13) Commission Delegated Directive 2014/13/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators ⁽⁷⁾ is to be incorporated into the EEA Agreement.
- (14) Commission Delegated Directive 2014/14/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for 3,5 mg mercury per lamp in single capped compact fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20 000 h ⁽⁸⁾ is to be incorporated into the EEA Agreement.
- (15) Commission Delegated Directive 2014/15/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer ⁽⁹⁾ is to be incorporated into the EEA Agreement.

⁽¹⁾ OJ L 4, 9.1.2014, p. 57.

⁽²⁾ OJ L 4, 9.1.2014, p. 59.

⁽³⁾ OJ L 4, 9.1.2014, p. 61.

⁽⁴⁾ OJ L 4, 9.1.2014, p. 63.

⁽⁵⁾ OJ L 4, 9.1.2014, p. 65.

⁽⁶⁾ OJ L 4, 9.1.2014, p. 67.

⁽⁷⁾ OJ L 4, 9.1.2014, p. 69.

⁽⁸⁾ OJ L 4, 9.1.2014, p. 71.

⁽⁹⁾ OJ L 4, 9.1.2014, p. 73.

- (16) Commission Delegated Directive 2014/16/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi₂O₅:Pb) phosphors⁽¹⁾ is to be incorporated into the EEA Agreement.
- (17) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following indents are added in point 12q (Directive 2011/65/EU of the European Parliament and of the Council) of Chapter XV of Annex II to the EEA Agreement:

- **32014 L 0001**: Commission Delegated Directive 2014/1/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 45),
- **32014 L 0002**: Commission Delegated Directive 2014/2/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 47),
- **32014 L 0003**: Commission Delegated Directive 2014/3/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 49),
- **32014 L 0004**: Commission Delegated Directive 2014/4/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 51),
- **32014 L 0005**: Commission Delegated Directive 2014/5/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 53),
- **32014 L 0006**: Commission Delegated Directive 2014/6/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 55),
- **32014 L 0007**: Commission Delegated Directive 2014/7/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 57),
- **32014 L 0008**: Commission Delegated Directive 2014/8/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 59),
- **32014 L 0009**: Commission Delegated Directive 2014/9/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 61),
- **32014 L 0010**: Commission Delegated Directive 2014/10/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 63),
- **32014 L 0011**: Commission Delegated Directive 2014/11/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 65),
- **32014 L 0012**: Commission Delegated Directive 2014/12/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 67),
- **32014 L 0013**: Commission Delegated Directive 2014/13/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 69),
- **32014 L 0014**: Commission Delegated Directive 2014/14/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 71),
- **32014 L 0015**: Commission Delegated Directive 2014/15/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 73),
- **32014 L 0016**: Commission Delegated Directive 2014/16/EU of 18 October 2013 (OJ L 4, 9.1.2014, p. 75).'

Article 2

The texts of Delegated Directives 2014/1/EU, 2014/2/EU, 2014/3/EU, 2014/4/EU, 2014/5/EU, 2014/6/EU, 2014/7/EU, 2014/8/EU, 2014/9/EU, 2014/10/EU, 2014/11/EU, 2014/12/EU, 2014/13/EU, 2014/14/EU, 2014/15/EU and 2014/16/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.

⁽¹⁾ OJ L 4, 9.1.2014, p. 75.

Article 3

This Decision shall enter into force on 28 June 2014, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

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, 27 June 2014.

For the EEA Joint Committee
The President
Gianluca GRIPPA

(*) No constitutional requirements indicated.