

## ANNEX IV

**Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments**

## Others

9. Cadmium in helium-cadmium lasers.
10. Lead and cadmium in atomic absorption spectroscopy lamps.
11. Lead in alloys as a superconductor and thermal conductor in MRI.
- [<sup>F1</sup>12. Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021.]

**Textual Amendments**

- F1** Substituted by [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 (Text with EEA relevance).

13. Lead in counterweights.
14. Lead in single crystal piezoelectric materials for ultrasonic transducers.
15. Lead in solders for bonding to ultrasonic transducers.
16. Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay.
17. Lead in solders in portable emergency defibrillators.
18. Lead in solders of high performance infrared imaging modules to detect in the range 8-14  $\mu\text{m}$ .
19. Lead in Liquid crystal on silicon (LCoS) displays.
20. Cadmium in X-ray measurement filters.
- [<sup>F2</sup>21. 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.]

**Textual Amendments**

- F2** Inserted by [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 (Text with EEA relevance).

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- [<sup>F3</sup>22. Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment. Expires on 30 June 2021.]

**Textual Amendments**

- F3** Inserted by 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 (Text with EEA relevance).

- [<sup>F4</sup>23. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.]

**Textual Amendments**

- F4** Inserted by 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 (Text with EEA relevance).

- [<sup>F5</sup>24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.]

**Textual Amendments**

- F5** Inserted by 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 (Text with EEA relevance).

- [<sup>F6</sup>25. 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. Expires on 30 June 2021.]

**Textual Amendments**

- F6** Inserted by 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 (Text with EEA relevance).

- [<sup>F7</sup>26. 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,

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— solders connecting transducers and sensors,

that are used durably at a temperature below – 20 °C under normal operating and storage conditions.

Expires on 30 June 2021.]

#### Textual Amendments

**F7** Inserted by [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 (Text with EEA relevance).

[<sup>F8</sup>27. 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 in

(a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or

(b) 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.

Expires on 30 June 2020.]

#### Textual Amendments

**F8** Inserted by [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 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 (Text with EEA relevance).

[<sup>F9</sup>28. Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards. Expires on 31 December 2017.]

#### Textual Amendments

**F9** Inserted by [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

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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 (Text with EEA relevance).

- [<sup>F10</sup>29. 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. Expires on 30 June 2021.]

**Textual Amendments**

- F10** Inserted by 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 (Text with EEA relevance).

- [<sup>F11</sup>30. 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.]

**Textual Amendments**

- F11** Inserted by 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 (Text with EEA relevance).

- [<sup>F12</sup>31. 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. Expires on 21 July 2021.]

**Textual Amendments**

- F12** Inserted by 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 (Text with EEA relevance).

- [<sup>F13</sup>32. 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. Expires on 31 December 2019.]

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#### Textual Amendments

**F13** Inserted by 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 (Text with EEA relevance).

[<sup>F14</sup>33. 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. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb.]

#### Textual Amendments

**F14** Inserted by 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 (Text with EEA relevance).

[<sup>F15</sup>34. Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi<sub>2</sub>O<sub>5</sub>:Pb) phosphors. Expires on 22 July 2021.]

#### Textual Amendments

**F15** Inserted by 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 (BaSi<sub>2</sub>O<sub>5</sub>:Pb) phosphors (Text with EEA relevance).