

ANNEX IV

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

Equipment utilising or detecting ionising radiation

1. Lead, cadmium and mercury in detectors for ionising radiation.
2. Lead bearings in X-ray tubes.
3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
4. Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.
5. Lead in shielding for ionising radiation.
6. Lead in X-ray test objects.
7. Lead stearate X-ray diffraction crystals.
8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers. Sensors, detectors and electrodes
 - 1a. Lead and cadmium in ion selective electrodes including glass of pH electrodes.
 - 1b. Lead anodes in electrochemical oxygen sensors.
 - 1c. Lead, cadmium and mercury in infra-red light detectors.
 - 1d. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.

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.
- [^{F1}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.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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 µm.
19. Lead in Liquid crystal on silicon (LCoS) displays.
20. Cadmium in X-ray measurement filters.
- [^{F2}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).

- [^{F3}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).

- [^{F4}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).

- [^{F5}24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.]

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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).

[^{F6}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).

[^{F7}26. Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:

- (a) solders on printed circuit boards;
- (b) termination coatings of electrical and electronic components and coatings of printed circuit boards;
- (c) solders for connecting wires and cables;
- (d) solders connecting transducers and sensors.

Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

These exemptions expire on 30 June 2021.]

Textual Amendments

- F7** Substituted by [Commission Delegated Directive \(EU\) 2016/1028 of 19 April 2016](#) 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 of electrical connections to temperature measurement sensors in certain devices (Text with EEA relevance).

[^{F8}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

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- (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).

- [^{F9}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 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).

- [^{F10}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).

- [^{F11}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.]

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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).

^{F12}31.

Textual Amendments

F12 Deleted by Commission Delegated Directive (EU) 2016/585 of 12 February 2016 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, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes (Text with EEA relevance).

[^{F13}31a. Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

Expires on:

- (a) 21 July 2021 for the use in medical devices other than *in vitro* diagnostic medical devices;
- (b) 21 July 2023 for the use in *in vitro* diagnostic medical devices;
- (c) 21 July 2024 for the use in electron microscopes and their accessories.]

Textual Amendments

F13 Inserted by Commission Delegated Directive (EU) 2016/585 of 12 February 2016 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, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes (Text with EEA relevance).

[^{F14}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.]

Textual Amendments

F14 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

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data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment (Text with EEA relevance).

- [^{F15}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

F15 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).

- [^{F16}34. Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi₂O₅:Pb) phosphors. Expires on 22 July 2021.]

Textual Amendments

F16 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 (BaSi₂O₅:Pb) phosphors (Text with EEA relevance).

- [^{F17}35. Mercury in cold cathode fluorescent lamps for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017

Expires on 21 July 2024.]

Textual Amendments

F17 Inserted by Commission Delegated Directive 2014/75/EU of 13 March 2014 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 mercury in cold cathode fluorescent lamps (CCFLs) for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017 (Text with EEA relevance).

- [^{F18}36. Lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments.

Expires on 31 December 2020. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.]

Textual Amendments

F18 Inserted by Commission Delegated Directive 2014/74/EU of 13 March 2014 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 used in other than C-press compliant pin connector systems for industrial monitoring and control instruments (Text with EEA relevance).

- [^{F19}37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:
- (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;
 - (b) measurements of solutions where an accuracy of +/- 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:
 - (i) solutions with an acidity < pH 1;
 - (ii) solutions with an alkalinity > pH 13;
 - (iii) corrosive solutions containing halogen gas;
 - (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.

Expires on 31 December 2018.]

Textual Amendments

F19 Inserted by [Commission Delegated Directive 2014/73/EU of 13 March 2014 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 platinized platinum electrodes used for conductivity measurements \(Text with EEA relevance\).](#)

- [^{F20}38. Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in X-ray detectors of computed tomography and X-ray systems.

Expires on 31 December 2019. May be used after that date in spare parts for CT and X-ray systems placed on the market before 1 January 2020.]

Textual Amendments

F20 Inserted by [Commission Delegated Directive 2014/71/EU of 13 March 2014 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 solder in one interface of large area stacked die elements \(Text with EEA relevance\).](#)

- [^{F21}39. Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:
- (a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;
 - (b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:

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- (i) a response time shorter than 25 ns;
 - (ii) a sample detection area larger than 149 mm²;
 - (iii) a multiplication factor larger than $1,3 \times 10^3$.
- (c) a response time shorter than 5 ns for detecting electrons or ions;
 - (d) a sample detection area larger than 314 mm² for detecting electrons or ions;
 - (e) a multiplication factor larger than $4,0 \times 10^7$.

The exemption expires on the following dates:

- (a) 21 July 2021 for medical devices and monitoring and control instruments;
- (b) 21 July 2023 for in-vitro diagnostic medical devices;
- (c) 21 July 2024 for industrial monitoring and control instruments.]

Textual Amendments

F21 Inserted by [Commission Delegated Directive 2014/70/EU of 13 March 2014 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 micro-channel plates \(MCPs\) \(Text with EEA relevance\).](#)

[^{F22}40. Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments.

Expires on 31 December 2020. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.]

Textual Amendments

F22 Inserted by [Commission Delegated Directive 2014/69/EU of 13 March 2014 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 dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments \(Text with EEA relevance\).](#)

[^{F23}41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on 31 December 2018.]

Textual Amendments

F23 Inserted by [Commission Delegated Directive \(EU\) 2015/573 of 30 January 2015 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 polyvinyl chloride sensors in in-vitro diagnostic medical devices \(Text with EEA relevance\).](#)

[^{F24}42. Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

Expires on 30 June 2019.]

Textual Amendments

F24 Inserted by [Commission Delegated Directive \(EU\) 2015/574 of 30 January 2015 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 mercury in intravascular ultrasound imaging systems \(Text with EEA relevance\).](#)

[^{F25}43. Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10 ppm is required.

Expires on 15 July 2023.]

Textual Amendments

F25 Inserted by [Commission Delegated Directive \(EU\) 2016/1029 of 19 April 2016 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 cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments \(Text with EEA relevance\).](#)