

SAFEGUARDS

CONSUMER GOODS AND RETAIL

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EU AMENDMENT OF RoHS EXEMPTIONS FOR MEDICAL DEVICES (ANNEX IV) AND FLUORESCENT LAMPS (ANNEX III)

From 22 July 2014 medical devices excluding active implantable medical devices (IVD) and from 22 July 2016 IVD need to comply with the RoHS recast¹. Due to various reasons, such as safety, a negative impact to environment or no substitutes, etc. the European Parliament and the Council have amended Annex IV of RoHS recast "2011/65/EU"¹.

Therefore on 9 January 2014 a total of 16 amendments to the RoHS Directive were published. 15 amendments affecting medical devices (Annex IV) were issued and there is a new exemption for mercury in certain compact fluorescent lamps which will be included in RoHS Annex III.

The codes of the issued amendments are COMMISSION DELEGATED DIRECTIVE 2014/1/EU to 2014/16/EU. Directive 2014/14/EU deals with mercury content of single capped fluorescence lamps. This Directive will amend the general RoHS Annex III whereas the other amendments affect RoHS Annex IV for medical devices.

In accordance with Article 4(1) of the RoHS recast¹ Member States shall ensure that electrical and electronic equipment placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the restricted substances beyond the thresholds set in RoHS Annex II. Because of various



reasons, such as the reliability of the substitutes, the negative impact to human health or environment or technical barrier, etc. the amendments of RoHS Annex IV specific to medical devices are necessary. Annex IV is separated into 3 groups. They are:

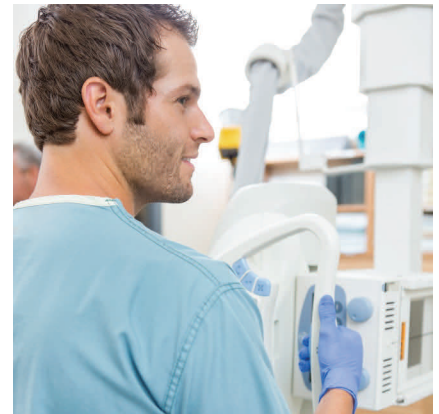
- Group 1: Equipment utilising or detecting ionising radiation
- Group 2: Sensors, detectors and electrodes
- Group 3: Others

¹ [RoHS recast](#)

The exemptions for the abovementioned second and third groups were revised during this serial amendment. The point 12 of RoHS Annex IV is replaced with a new one. 14 new exemptions from the point 21 to 34 are added to the third group. In addition all the amendments have accompanied expiry dates.

According to the Article 2 of all the abovementioned amendments, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with RoHS recast by the last day of the sixth month after these amendments entering into force at the latest.

SGS has consolidated all the exemptions specific to medical devices below.



APPLICATIONS EXEMPTED FROM THE RESTRICTION IN ARTICLE 4(1) SPECIFIC TO MEDICAL DEVICES

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.
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 ² .
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 μm .
19	Lead in Liquid crystal on silicon (LCoS) displays.
20	Cadmium in X-ray measurement filters. EN L 174/106 Official Journal of the European Union 1.7.2011
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 ³ .
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 ⁴ .
23	Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021 ⁵ .
24	Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019 ⁶ .
25	Lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below $-20\text{ }^{\circ}\text{C}$ under normal operating and storage conditions. Expires on 30 June 2021 ⁷ .

² [COMMISSION DELEGATED DIRECTIVE 2014/1/EU](#)

³ [COMMISSION DELEGATED DIRECTIVE 2014/2/EU](#)

⁴ [COMMISSION DELEGATED DIRECTIVE 2014/3/EU](#)

⁵ [COMMISSION DELEGATED DIRECTIVE 2014/4/EU](#)

⁶ [COMMISSION DELEGATED DIRECTIVE 2014/5/EU](#)

⁷ [COMMISSION DELEGATED DIRECTIVE 2014/6/EU](#)

⁸ [COMMISSION DELEGATED DIRECTIVE 2014/7/EU](#)

OTHERS	
26	<p>Lead in</p> <ul style="list-style-type: none"> • 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. <p>Expires on 30 June 2021⁸.</p>
27	<p>Lead in</p> <ul style="list-style-type: none"> • solders, • termination coatings of electrical and electronic components and printed circuit boards, • connections of electrical wires, shields and enclosed connectors, <p>which are used in</p> <ol style="list-style-type: none"> 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. <p>Expires on 30 June 2020⁹.</p>
28	<p>Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards.</p> <p>Expires on 31 December 2017¹⁰.</p>
29	<p>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 2021¹¹.</p>
30	<p>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 2020¹².</p>
31	<p>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 2021¹³.</p>
32	<p>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 2019¹⁴.</p>
33	<p>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 IIb¹⁵.</p>
34	<p>Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi 2 O 5 :Pb) phosphors. Expires on 22 July 2021¹⁶.</p>

⁸ [COMMISSION DELEGATED DIRECTIVE 2014/7/EU](#)

⁹ [COMMISSION DELEGATED DIRECTIVE 2014/8/EU](#)

¹⁰ [COMMISSION DELEGATED DIRECTIVE 2014/9/EU](#)

¹¹ [COMMISSION DELEGATED DIRECTIVE 2014/10/EU](#)

¹² [COMMISSION DELEGATED DIRECTIVE 2014/11/EU](#)

¹³ [COMMISSION DELEGATED DIRECTIVE 2014/12/EU](#)

¹⁴ [COMMISSION DELEGATED DIRECTIVE 2014/13/EU](#)

¹⁵ [COMMISSION DELEGATED DIRECTIVE 2014/15/EU](#)

¹⁶ [COMMISSION DELEGATED DIRECTIVE 2014/16/EU](#)

APPLICATIONS EXEMPTED FROM THE RESTRICTION IN ARTICLE 4(1) SPECIFIC TO MERCURY IN SINGLE END CAPPED FLUORESCENCE LAMPS

1 (g)	For general lighting purposes <30 W with a lifetime equal or above 20 000 h: 3,5 mg Expires on 31 December 2017 ¹⁷ .
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Whether you are in need of hazardous substances testing or other third party verification, certification or inspection services, SGS is ideally positioned to satisfy all your business's needs. www.sgs.com/cgnr



¹⁷ [COMMISSION DELEGATED DIRECTIVE 2014/14/EU](http://www.sgs.com/cgnr)

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