

Tel. +1 514 887-7871 / www.getenviropass.com

EU RoHS Exemption list (Annex IV)*

Medical Devices and Monitoring and Control Instruments

Exemption #	Description	Scope and Expiration Dates (if any)
1	Lead, cadmium and mercury in detectors for ionising radiation.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices).
1a	Sensors, detectors and electrodes - Lead and cadmium in ion selective electrodes including glass of pH electrodes.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices).
1b	Sensors, detectors and electrodes - Lead anodes in electrochemical oxygen sensors.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices).
1c	Sensors, detectors and electrodes - Lead, cadmium and mercury in infra-red light detectors.	Applies to categories 8 and 9.
1d	Sensors, detectors and electrodes - Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.	Applies to categories 8 (other than in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments).
2	Equipment utilising or detecting ionising radiation - Lead bearings in X-ray tubes.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
3	Equipment utilising or detecting ionising radiation - Lead in electromagnetic radiation amplification devices: micro- channel plate and capillary plate.	Applies to categories 8 and 9.
4	Equipment utilising or detecting ionising radiation - 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.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
5	Equipment utilising or detecting ionising radiation - Lead in shielding for ionising radiation.	Applies to categories 8 and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices).
6	Equipment utilising or detecting ionising radiation - Lead in X-ray test objects.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for category 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).

7	Equipment utilising or detecting ionising radiation - Lead stearate X-ray diffraction crystals.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for category 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
8	Equipment utilising or detecting ionising radiation - Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for category 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
9	Others - Cadmium in helium-cadmium lasers.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for category 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
10	Others - Lead and cadmium in atomic absorption spectroscopy lamps.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for category 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
11	Others - Lead in alloys as a superconductor and thermal conductor in MRI.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments)
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.	Applies to categories 8 (other than in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments).
13	Others - Lead in counterweights.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
14	Others - Lead in single crystal piezoelectric materials for ultrasonic transducers.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).

15	Others - Lead in solders for bonding to ultrasonic transducers.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
16	Others - 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.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments)
17	Others - Lead in solders in portable emergency defibrillators.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
18	Others - Lead in solders of high performance infrared imaging modules to detect in the range 8-14 $\mu m.$	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
19	Others - Lead in Liquid crystal on silicon (LCoS) displays.	Applies to categories 8 (in vitro diagnostic medical devices) and 9 (industrial monitoring and control instruments). Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments)
20	Others - Cadmium in X-ray measurement filters.	Applies to categories 8 and 9. Expires on: — 21 July 2023 for categories 8 (in vitro diagnostic medical devices). — 21 July 2024 for category 9 (industrial monitoring and control instruments).
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.	Expired on 31 December 2019
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.	Expired on 30 June 2021
23	Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation.	Expired on 30 June 2021
24	Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers.	Expired on 31 December 2019
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.	Expired on 30 June 2021

	1	1
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.	Applies to categories 8 (other than in vitro diagnostic medical devices) and 9.
27	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.	Applies to categories 8 and 9 (other than industrial monitoring and control instruments).
28	Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards.	Expired on 31 December 2017
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.	Applies to categories 8 (other than in vitro diagnostic medical devices) and 9 (other than industrial monitoring and control instruments).
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.	Expired on 31 December 2019
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.	Expired on 5 November 2017
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.	Applies to categories 8 and 9. Expires on: — 21 July 2024 for category 9 (industrial monitoring and control instruments).

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.	Expired on 31 December 2019
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.	Expried on 30 June 2016 for class IIa and 31 December 2020 for class IIb.
34	Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors.	Expired on 22 July 2021.
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.	Applies to category 9 (industrial monitoring and control instruments). Expires on 21 July 2024.
36	Lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments.	Expired on 31 December 2020.
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 +/C 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.	Applies to categories 8 and 9. Expires on 31 December 2025.
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.	Expired on 31 December 2019.

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: (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 × 103. (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 × 107.	Applies to categories 8 and 9.
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.	Expired on 31 December 2020
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.	Applies to category 8 (in vitro diagnostic medical devices) Expires on 31 March 2022
42	Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50MHz) modes of operation.	Applies to categories 8 (other than in vitro diagnostic medical devices) and 9 (other than industrial monitoring and control instruments). Expires on 30 June 2026
43	Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10 ppm is required.	Applies to category 9 (industrial monitoring and control instruments). Expires on 15 July 2023
44	Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy.	Applies to category 8 (other than in vitro diagnostic medical devices) and 9. Expires on 31 March 2027

* Note: This is a simplified list. Enviropass Expertise Inc. does not warrant the accuracy or completeness of this document. The opinion expressed in this document is only that of the Enviropass Expertise Inc and does not constitute legal advice. Technical and compliance specifications and any other materials or information provided are subject to change without notice and reliance on its contents shall be at your sole risk.