

RoHS2.0 指令附件 IV 豁免清单

(适用于医疗设备及监视和控制设备)

Equipment utilising or detecting ionising radiation

利用或检测电离辐射的设备：

1. Lead, cadmium and mercury in detectors for ionising radiation.
电离辐射探测器中的铅、镉和汞。
2. Lead bearings in X-ray tubes.
X 射线管中的铅轴承。
3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
电磁辐射放大设备中的铅：微通道板和毛细管板。
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.
X 射线管和图像增强器中的铅，将电磁辐射转换为电子的真空管和气体激光器中玻璃熔料中的铅。
5. Lead in shielding for ionising radiation.
电离辐射屏蔽设置中的铅。
6. Lead in X-ray test objects.
X 射线测试物的铅。
7. Lead stearate X-ray diffraction crystals.
硬脂酸铅 X 射线衍射晶体。
8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.
便携式 X 射线荧光光谱仪中的放射性镉同位素源。

Sensors, detectors and electrodes :

传感器、检测器与电极：

- 1a. Lead and cadmium in ion selective electrodes including glass of pH electrodes.
离子选择性电极，包括玻璃 pH 电极中的铅和镉。
- 1b. Lead anodes in electrochemical oxygen sensors.
电化学氧传感器中的铅阳极。
- 1c. Lead, cadmium and mercury in infra-red light detectors.
红外检测器中的铅、镉和汞。
- 1d. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.
参比电极中的汞：低氯化汞、硫酸汞和氧化汞。

Others

其他

9. Cadmium in helium-cadmium lasers.
氦-镉激光器中的镉。
10. Lead and cadmium in atomic absorption spectroscopy lamps.
原子吸收光谱灯中的铅和镉。
11. Lead in alloys as a superconductor and thermal conductor in MRI.
MRI 热导体和超导合金中的铅。
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.
MRI, SQUID, NMR (核磁共振) 或 FTMS (傅里叶变换质谱仪) 检测器中创建超导磁回路的金属键中的铅和镉。2021 年 6 月 30 日到期。
13. Lead in counterweights.
配重铅。
14. Lead in single crystal piezoelectric materials for ultrasonic transducers.
超声换能器单晶压电材料中的铅。
15. Lead in solders for bonding to ultrasonic transducers.
用于粘结超声换能器的焊料中的铅。
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.
高精度电容和损耗测量电桥中的汞、监控设备所用高频 RF 开关或继电器中的汞，每个开关或继电器中的汞含量不超过 20mg 的汞。
17. Lead in solders in portable emergency defibrillators.
便携式紧急心脏起搏器中的焊料中的铅。
18. Lead in solders of high performance infrared imaging modules to detect in the range 8-14 μm .
检测范围为 8-14 微米的高性能红外成像模块焊料中的铅。
19. Lead in Liquid crystal on silicon (LCoS) displays.
硅基液晶显示器中的铅。
20. Cadmium in X-ray measurement filters.

X 射线测量过滤器中的镉。

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.

2019 年 12 月 31 日前的 X 射线影像增强器和 2020 年 1 月 1 日前投放欧盟市场的 X 射线系统备用部件中的荧光粉涂层中的镉。

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.

用于与 CT 和 MRI 配套使用的立体定向头架和 γ 射线以及粒子治疗设备的定位系统中的醋酸铅标记。2021 年 6 月 30 日到期。

23. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.

暴露在电离辐射中的医疗设备轴承和磨损面中作为合金元素的铅。2021 年 6 月 30 日到期。

24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.

促使 X 射线影像增强器中的铝和钢之间真空密封连接的铅。2019 年 12 月 31 日到期。

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.

在正常操作和储存条件下可在 -20°C 以下持续使用的，要求使用非磁性连接器的针连接系统表面涂层的铅。2021 年 6 月 30 日到期。

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.

正常操作和存放环境下，长期在低于 -20°C 温度下工作的以下用途中的铅：

- (a) 印刷电路板的焊料；
- (b) 电子电气零部件的终端涂层和印刷电路板的涂层；
- (c) 连接电线电缆的焊料；
- (d) 连接转换器和传感器的焊料；

周期性地用于低于 -150°C 的设备中的测温传感器的电气连接焊料中的铅。

2021 年 6 月 30 日到期。

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.

铅用于

— 焊料,

— 电子电气元件和印刷电路板的绝缘涂层,

— 连接电线, 屏蔽套和封闭式连接器,

以上用于

(a) 医用磁共振成像设备磁铁中心 1 米半径范围内的磁场, 包括设计用于该范围内的病人监护仪, 或

(b) 回旋加速器磁铁以及用于粒子治疗的束流传输和光速方向控制的磁铁外表面 1m 距离范围内的磁场。

2020 年 6 月 30 日到期。

28. Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards. Expires on 31 December 2017.
用于将碲化镉和碲化镉锌数字阵列探测器封装到印刷电路板上的焊料中的铅。2017 年 12 月 31 日到期。
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.
作为超导体或导热体的合金中的铅, 用于医疗设备 (第 8 类) 和/或工业监控设备中的低温冷却器冷头和/或低温冷却冷探针和/或低温冷却等电位连接系统。2021 年 6 月 30 日到期。
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.
2019 年 12 月 31 日前的 X 射线影像增强器和 2020 年 1 月 1 日前投放欧盟市场的 X 射线系统备用部件中用于形成光电阴极的碱金属释放剂中的六价铬。
- 31(a). 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.'

自维修或翻新的医疗设备中回收的，以及供维修或翻新的医疗设备（包括体外诊断设备及电子显微镜及其配件）使用的零部件中的铅、镉、六价铬以及 PBDE。假设再使用是在审核闭环的商对商的回收系统中及部件的再使用已向消费者通报。

(a) 除体外诊断医疗设备外的医疗设备截止到 2021 年 7 月 21 日；

(b) 体外诊断医疗设备截止到 2023 年 7 月 21 日；

(c) 电子显微镜及其附件截止到 2024 年 7 月 21 日。

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.
用于磁共振成像设备中集成的正电子发射计算机断层扫描探测器和数据采集单元印刷电路板焊料中的铅。2019 年 12 月 31 日到期。
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.
用于指令 93/42/EEC 中类别 IIa 和 IIb 的移动医疗设备的带元件印刷电路板焊料中的铅，便携式应急除颤器除外。
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.
用作光致迁动灯（含磷光粉 BSP (BaSi₂O₅:Pb)）的放电灯中的荧光粉的激活剂中的铅。2021 年 7 月 22 日到期。
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.
用作 2017 年 7 月 22 日前投放市场的工业监控设备中背光液晶显示器的冷阴极荧光灯（CCFLs）的汞，每盏灯不超过 5 毫克。2024 年 7 月 21 日到期。
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.
用作工业监控设备中除 C-press 之外的顺应针连接器系统中的铅。2020 年 12 月 31 日前到期，之后仅可用作 2021 年 1 月 1 日前投放市场的工业监控设备的备用部件。
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.

用作电导率测试的铂黑电极中的铅。铂黑电极须满足至少一个条件：

- (a) 跨数量级的宽范围电导率测量（例如范围在 0.1 毫秒/米和 5 毫秒/米）；
- (b) 用于高腐蚀性溶液电导率的测量，测量精度为±1%，溶液 pH 值小于 1 或大于 13，或含卤素气体的腐蚀性溶液；
- (c) 用于测量电导率高于 100 毫秒/米的便携式仪器。

2018 年 12 月 31 号到期。

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.

用作 X 射线计算机断层扫描探测设备与 X 射线系统中的具有超过 500 个互连接口的大面积堆叠芯片元件接口上的焊料中的铅。2019 年 12 月 31 日到期，之后仅可用于 2020 年 1 月 1 日前投放市场的 CT 和 X 射线系统的备用部件。

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. 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.

具有特定性能参数的设备中的微通道板(MCPs)中的铅。此设备需满足至少一个条件：

- (a) 紧凑型电子或离子检测器，检测器的空间最大为 3 毫米/MCP（检测器厚度+MCP 安装空间），最大总尺寸 6 毫米，并且扩大检测器空间的替代设计在科学和技术上不可行；
- (b) 二维空间分辨率，可用于检测电子或离子，至少满足一项：(i) 响应时间少于 25n 纳秒，(ii) 样品检测区域大于 149 平方毫米；(iii) 乘法因子大于 1,3×10³；
- (c) 响应时间少于 5 纳秒的电子或离子检测器；
- (d) 样品检测区域大于 314 平方毫米；
- (e) 乘法因子大于 4.0×10⁷.

该豁免到期日：

- (a) 医疗器械及监视和控制设备：2021 年 7 月 21 日；
- (b) 体外诊断医疗器械，2023 年 7 月 21 日；
- (c) 工业监控设备，2024 年 7 月 21 日。

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.

用作工业监控设备中额定电压小于 125V AC 或 250V DC 的电容器中的介电陶瓷中的铅。2020 年 12 月 31 日到期，之后仅可用于 2021 年 1 月 1 日前投放市场的工业监控设备的备用部件。

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.

用作血液及其他液体、体气分析的体外诊断医疗设备中电位、电流、电导传感器聚氯乙烯(PVC)基材中作为热稳定剂的铅。2018 年 12 月 31 日到期。

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.

用作具有高工作频率 (> 50MHz) 操作模式的血管内超声成像系统中的电旋转连接器中的汞。2019 年 6 月 30 日到期。

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.

用于工业监测和控制设备的氧传感器的赫希池镉阳极，灵敏度应低于 10ppm。2023 年 7 月 15 日到期。

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