

Applications exempted from the EU RoHS Directive (revised ver.) (Attachment IV: only for medical devices and monitoring and control equipment)  
 (改正RoHSの適用除外用途 (附属書IV：医用機器と監視制御機器のみ))

\* As for latest each exemption, please refer to the original directive for confirmation.  
 (改正RoHS指令の各適用除外項目の最新情報については、法律原文をご参照・確認ください)

Source:  
 (情報源と更新情報:  
 参考URL:

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS)  
 RoHS Directive)  
[https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive\\_en](https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en)

Original	Japanese translation for reference 日本語参考訳	Scope and dates of applicability	Related substances (関係する物質)								Remarks (備考)
			Cd	Cr <sup>6+</sup>	Hg	Pb	DEHP	BBP	DBP	DIBP	
<b>ANNEX IV "Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments"</b>											
<b>Equipment utilising or detecting ionising radiation</b>											
電離放射線の利用または検出に使用される機器											
1	Lead, cadmium and mercury in detectors for ionising radiation.	電離放射線検出器に含まれる鉛、カドミウムおよび水銀	Currently under review in EU (Cat.8,9 others,Cat.9 industrial) 21 July 2023 (Cat.8 in vitro)	○		○	○				
2	Lead bearings in X-ray tubes.	X線管の鉛ベアリング	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.	電離放射線の増幅デバイス(マイクロチャンネルプレートとキャピラリープレート)に含まれる鉛	Currently under review in EU (Cat.8,9)				○				
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線管および蛍光増倍管用のガラスフリット中に含まれる鉛、並びにガスレーザーの組立て用および電離放射線を電子に変換する真空管用のガラスフリットバイндаに含まれる鉛	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) Currently under review in EU (Cat.9 industrial)				○				
5	Lead in shielding for ionising radiation.	電離放射線のシールドに含まれる鉛	Currently under review in EU (Cat.8,9 others,Cat.9 industrial) 21 July 2023 (Cat.8 in vitro)				○				
6	Lead in X-ray test objects.	X線試験体に含まれる鉛	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
7	Lead stearate X-ray diffraction crystals.	X線回折結晶のステアリン酸鉛	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
8	Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.	ポータブルX線蛍光分析装置用の放射性カドミウム同位体線源	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)	○							
<b>Sensors, detectors and electrodes</b>											
センサー、検出器、電極											
1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes.	pH電極のガラスを含むイオン選択性電極に含まれる鉛とカドミウム	Currently under review in EU (Cat.8,9)	○			○				
1b	Lead anodes in electrochemical oxygen sensors.	電気化学的酸素センサーの鉛陽極	Currently under review in EU (Cat.8,9 others,Cat.9 industrial) 21 July 2023 (Cat.8 in vitro)				○				
1c	Lead, cadmium and mercury in infra-red light detectors.	赤外線検出器に含まれる鉛、カドミウム、水銀	Currently under review in EU (Cat.8,9)	○		○	○				
1d	Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.	基準電極に含まれる水銀(低塩素の塩化水銀、硫酸水銀および酸化水銀)	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)			○					
<b>Others</b>											
その他											
9	Cadmium in helium-cadmium lasers.	He-Cdレーザーに含まれるカドミウム	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) Currently under review in EU (Cat.9 industrial)	○							
10	Lead and cadmium in atomic absorption spectroscopy lamps.	原子吸光分析装置のランプに含まれる鉛とカドミウム	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) Currently under review in EU (Cat.9 industrial)	○			○				
11	Lead in alloys as a superconductor and thermal conductor in MRI.	MRI (磁気共鳴画像診断装置) の超伝導体および熱伝導体の合金に含まれる鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
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.	MRI (磁気共鳴画像診断装置)、SQUID (超伝導量子干渉計)、NMR (Nuclear Magnetic Resonance) (磁気共鳴) または FTMS (Fourier Transform Mass Spectrometer) (フーリエ変換質量分析計) 検出器の超伝導磁気回路を構成している金属結合中に含まれる鉛およびカドミウム。	Currently under review in EU (Cat.8,9 others,Cat.9 industrial) 30 June 2021 (Cat.8 in vitro)	○			○				Replaced in the Official Journal of the European Union L4 on Oct. 18, 2013 (2013.10.18 官報L4置き換え)
13	Lead in counterweights.	カウンタウエイト中の鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
14	Lead in single crystal piezoelectric materials for ultrasonic transducers.	超音波振動子用の単結晶ピエゾ(圧電)材料に含まれる鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
15	Lead in solders for bonding to ultrasonic transducers.	超音波振動子の接合用はんだに含まれる鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
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.	超高精度キャパシタンスおよび損失測定ブリッジに含まれる水銀および監視および制御機器に使われる高周波RFスイッチおよびリレーに含まれる1スイッチまたは1リレーあたり20mgを超えない水銀	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)			○					
17	Lead in solders in portable emergency defibrillators.	ポータブル緊急除細動器のはんだに含まれる鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
18	Lead in solders of high performance infrared imaging modules to detect in the range 8-14 μm.	8-14μm域の検出用の高性能赤外線画像モジュールのはんだに含まれる鉛	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
19	Lead in Liquid crystal on silicon (LCoS) displays.	LCoS (反射型液晶表示パネル) ディスプレイに含まれる鉛	21 July 2021 (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)				○				
20	Cadmium in X-ray measurement filters.	X線測定フィルターに含まれるカドミウム	Currently under review in EU (Cat.8,9 others) 21 July 2023 (Cat.8 in vitro) 21 July 2024 (Cat.9 industrial)	○							
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.	(1) 2019年12月31日までのX線画像用イメージインテンシファイア中の蛍光体コーティング (2) 2020年1月1日以前にEU市場に上市されたX線システム用スペアパーツ中に含まれるカドミウム	(1)31 December 2019 (2)No deadline	○							Added in the Official Journal of the European Union L4 on Oct. 18, 2013 (2013.10.18 官報L4追加)
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.	CTおよびMRI用の定位ヘッドフレーム、およびガンマ線および粒子線治療装置のための位置決め装置に用いられる酢酸鉛マーカー。 有効期限：2021年6月30日	30 June 2021				○				Added in the Official Journal of the European Union L4 on Oct. 18, 2013 (2013.10.18 官報L4追加)
23	Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.	電離放射線にさらされる医療機器のベアリングおよび摩擦表面のための合金要素としての鉛。 有効期限：2021年6月30日	30 June 2021				○				Added in the Official Journal of the European Union L4 on Oct. 18, 2013 (2013.10.18 官報L4追加)
24	Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.	X線イメージインテンシファイア中のアルミニウムと鉄の間の真空気密接続を可能にする鉛。 有効期限：2019年12月31日	31 December 2019				○				Invalid Added in the Official Journal of the European Union L4 on Oct. 18, 2013 (無効 2013.10.18官報L4追加)
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.	通常動作および貯蔵状態でマイナス20°C以下の温度で永続的に使用されている非磁性コネクタを必要とするピンコネクタシステムの表面コーティングに含まれる鉛。 有効期限：2021年6月30日	30 June 2021				○				Added in the Official Journal of the European Union L4 on Oct. 18, 2013 (2013.10.18 官報L4追加)



Original	Japanese translation for reference 日本語参考訳	Scope and dates of applicability	Related substances (関係する物質)							Remarks (備考)	
			Cd	Cr <sup>VI</sup>	Hg	Pb	DEHP	BBP	DBP		DIBP
<b>ANNEX IV "Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments"</b>											
<b>付属文書IV「4条(1)による禁止の医用機器や監視制御機器における適用除外用途」</b>											
<b>法規制適用除外期限</b>											
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.	CTとX線装置のX線検出器で使用される、境界面あたり500を超える相互接続を有する広面積ダイエレクトロンの1階層面のはんだ中の鉛。 有効期限2019年12月31日。 2020年1月1日より前に上市されたCTとX線装置用のスペアパーツについてはこの期限以降も使用可能。	31 December 2019								Added in the Official Journal of the European Union L148 on Mar. 13, 2014 (2014.3.13 官報L148追加)
	Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:	以下の特性の少なくとも1つが存在する装置で使われるマイクロチャンネルプレート (MCPs) 中の鉛:									Added in the Official Journal of the European Union L148 on Mar. 13, 2014 (2014.3.13 官報L148追加)
39	(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 1.3 × 10 <sup>3</sup> ; (iii) a multiplication factor larger than 1.3 × 10 <sup>3</sup> ; (c) a response time shorter than 5 ns for detecting electrons or ions; (d) a sample detection area larger than 314 mm <sup>2</sup> for detecting electrons or ions; (e) a multiplication factor larger than 4.0 × 10 <sup>3</sup> .  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.	(a)最高3mm/MCP (検出器の厚さ+MCP設置スペース)、全体で最高6mmを限度としたスペースの小さいサイズの電子またはイオン検出器ならびにより大きいスペースを必要とする代替設計でない科学技術的に代替不可能な検出器 (b)以下の少なくとも1つが適用される電子またはイオン検出器の二次元的空間分解能: (i) 25nsより短い応答時間 (ii) 149mm <sup>2</sup> より大きな検出領域 (iii) 1.3×10 <sup>3</sup> より大きい増倍率 (c)電子またはイオン検出器の5nsより短い応答時間; (d)電子またはイオン検出器の314mm <sup>2</sup> より大きな検出領域 (e)4.0×10 <sup>3</sup> より大きい増倍率  適用除外の有効期限は次の通り。 (a)医療装置と監視および制御装置: 2021年7月21日 (b)体外診断用医療機器: 2023年7月21日 (c)産業用の監視および制御装置: 2024年7月21日	Currently under review in EU (Cat.8,9)								
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. 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.	産業用の監視および制御装置用の定格電圧AC125VまたはDC250Vより小さいコンデンサの中の誘電セラミック中の鉛。 有効期限: 2020年12月31日。 2021年1月1日より前に上市された産業用の監視および制御装置用のスペアパーツについてはこの期限以降も使用可能	31 December 2020								Added in the Official Journal of the European Union L148 on Mar. 13, 2014 (2014.3.13 官報L148追加)
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.	血液、他の体液、体内ガス分析のために体外診断用医療機器で使われる電流、電位差、導電率の電気化学的センサー中の主成分材料として使われるポリ塩化ビニル (PVC) 中の熱安定剤としての鉛。 有効期限: 2018年12月31日	31 December 2018								Replaced in the Official Journal of the European Union L94 on Mar. 5, 2020 (2020.3.5 官報L94置き換え)
41a	Lead as a thermal stabilizer 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 creatinine and blood urea nitrogen in whole blood. Applies to category 8 and expires on 31 December 2023.	全血中のクレアチニンおよび血尿酸濃度の分析のための体外診断用医療機器に用いられる電流測定、電位差測定および導電率測定に係る電気化学センサー中の基材として用いられるポリ塩化ビニル (PVC) 中の熱安定剤としての鉛 カテゴリ-8(医療機器)に適用。 有効期限: 2023年12月31日	31 December 2023								
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 2026.	高周波 (>50MHz) モードで運転可能な血管内超音波画像処理システムで使われる電気回転コネクタ中の水銀。 有効期限: 2026年6月30日	30 June 2026								Added in the Official Journal of the European Union L94 on Mar. 30, 2015 (2015.1.30 官報L94追加)
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.	10ppm未満の感度が要求される産業用監視・制御装置で使用される酸素センサーのためのエルシュセル (ハッシュセル) 中のカドミウムアノード。 有効期限: 2023年7月15日	15 July 2023								Added in the Official Journal of the European Union L168 on Apr. 19, 2016 (2016.4.19 官報L168追加)
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 9. Expires on 31 March 2027.	10ppm未満の感度が要求される産業用監視・制御装置で使用される酸素センサーのためのエルシュセル (ハッシュセル) 中のカドミウムアノード カテゴリ-9に適用。 有効期限: 2027年3月31日まで	31 March 2027 (Cat.8,9 others, Cat9 industrial)								Added in the Official Journal of the European Union L67 on Mar. 5, 2020 (2020.3.5 官報L67追加)
45	Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. Expires on 21 July 2028.	体液や透析液に依存するイオン性物質のポイントオブケア分析に使用されるイオン選択性電極中のフタル酸ビス(2-エチルヘキシル)(DEHP) 有効期限: 2028年7月21日	21 July 2028 (Cat.8 in vitro)								Added in the Official Journal of the European Union L402 on Aug. 11, 2021 (2021.8.11 官報L402追加)
46	Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils. Expires on 1 January 2024.	MRI 検出器コイルのプラスチック部品中のフタル酸ビス(2-エチルヘキシル)(DEHP) 有効期限: 2024年1月1日	Currently under review in EU (Cat.8 in vitro) 1 January 2024								Added in the Official Journal of the European Union L402 on Aug. 11, 2021 (2021.8.11 官報L402追加)
47	Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, 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 21 July 2028.	体外診断用医療機器を含む医療機器およびその付属品の修理またはリファービッシュのために回収され使用される、スペアパーツ中のフタル酸ビス(2-エチルヘキシル)(DEHP)、フタル酸ブチルベンジル(BBP)、フタル酸ジ-n-ブチル(DBP)およびフタル酸ジイソブチル (DIBP)、ただし、再利用が監視可能なクローズドループのB to B返却システムにおいて起こり、かつ、その再利用が消費者に通知されることを条件とする 有効期限: 2028年7月21日	21 July 2028 (Cat.8 in vitro)								Added in the Official Journal of the European Union L402 on Aug. 11, 2021 (2021.8.11 官報L402追加)
48	Lead in bismuth strontium calcium copper oxide (BSCCO) superconductor cables and wires and lead in electrical connections to these wires Expires on 30 June 2027.	ビスマスストロンチウムカルシウム銅酸化物 (BSCCO) 超電導ケーブルおよびワイヤー内の鉛、およびこれらのワイヤーへの電気接続内の鉛。 有効期限: 2027年6月30日	30 June 2027								Added in the Official Journal of the European Union L245 on Sep. 22, 2022 (2022.9.22 官報L245追加)
49	Mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and pressures over 1000bar Applies to category 9 and expires on 31 December 2025.	300 °Cを超える温度および、1000 barを超える圧力におけるキャピラリーレオメーターの溶融圧力トランスデューサー内の水銀。 カテゴリ-9に適用され、有効期限は2025年12月31日。	31 December 2025 (Cat.9 in vitro)								2023年7月11日、官報(EU)2023/1437