

COCIR / BOMcheck List of Restricted and Declarable Substances for Medical Devices

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. [BOMcheck](#) is an industry collaboration sharing one cloud-based platform to manage supply chain compliance with substance regulations around the world. The list is managed by the COCIR EHS Committee and BOMcheck Substance List Working Group and is aligned with the IPC-1752A and IPC-1752B Standard for Materials Declaration Management (<http://www.ipc.org/ContentPage.aspx?pageid=Materials-Declaration>) and the IEC 62474 screening of REACH Candidate List Substances.

1. Product restrictions

Primary Declarable Substance Lists (Primary DSLs)

Restriction of Certain Hazardous Substances (RoHS) Directive 2011/65/EU

The RoHS substance restrictions apply to every individual homogenous material in the part. BOMcheck is aligned with the IPC 1752A substance category list EUROHS-0508. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for the substances which are included in each RoHS substance group.

Appendix A provides the list of exemptions published in Annex III of the RoHS Directive 2011/65/EU and Appendix B provides the list of exemptions published in Annex IV of the RoHS Directive 2011/65/EU. A declaration containing the worst-case concentration of these substances is required to calculate compliance when the exemption expires in the future. Note that these substance exemptions in the EU RoHS Directive do not provide any exemption from the product labelling requirements in China RoHS – the substances must be listed in the marking table.

Substance group	Maximum concentration of the substance in any individual homogenous material in the part	Threshold calculation level
Cadmium/cadmium compounds	0.01% by weight (100 ppm) of homogeneous materials	Material
Hexavalent Chromium compounds	0.1% by weight (1 000 ppm) of homogeneous materials	Material
Lead/lead compounds	0.1% by weight (1 000 ppm) of homogeneous materials	Material
Mercury/mercury compounds	0.1% by weight (1 000 ppm) of homogeneous materials	Material
PBBs	0.1% by weight (1 000 ppm) of homogeneous materials	Material
PBDEs	0.1% by weight (1 000 ppm) of homogeneous materials	Material

RoHS substance restrictions amendment 1 (Directive 2011/65/EU, as amended by Directive (EU) 2015/863 of March 2015)

On 4 June 2015 the European Commission published Delegated Directive 2015/863 which officially adds four new substances and maximum concentration values in homogenous materials to Annex II of the RoHS Directive. Electrical and electronic equipment must comply with these additional substance restrictions from 22 July 2019, except for Medical Devices (Category 8) and Monitoring and Control Instruments (Category 9) which must comply with these additional substance restrictions from 22 July 2021.

Substance group	Maximum concentration of the substance in any individual homogenous material in the part	Threshold calculation level
Bis(2-ethylhexyl) phthalate (DEHP)	0.1% by weight (1 000 ppm) of homogeneous materials	Material
Butyl benzyl phthalate (BBP)	0.1% by weight (1 000 ppm) of homogeneous materials	Material
Dibutyl phthalate (DBP)	0.1% by weight (1 000 ppm) of homogeneous materials	Material
Diisobutyl phthalate (DIBP)	0.1% by weight (1 000 ppm) of homogeneous materials	Material

Registration Evaluation Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006 (as amended)

REACH Candidate List substances found in supplied articles

REACH Article 33 requires all suppliers to inform their customers if the product they supply includes any article that contains any of the substances in the Candidate List in concentrations > 0.1% w/w of the article. An article is any item that has a special shape, surface or design which determines its function to a greater degree than its chemical composition (e.g. a screw, resistor, wire). Please note that this definition of an article may apply to individual components in your product. For further guidance on what is considered an article under the REACH Regulation please refer to the ECHA Guidance published at https://echa.europa.eu/documents/10162/2324906/articles_en.pdf

There are 247 Substances of Very High Concern (SVHCs) on the current REACH Candidate List published 21 January 2025 at <https://echa.europa.eu/candidate-list-table>. BOMcheck has determined that 122 of these SVHCs are not normally found in concentrations > 0.1% w/w in supplied articles. If parts and materials are manufactured using conventional industry processes, then the supplier can rely on the BOMcheck guidance and screen out these 122 SVHCs (BOMcheck will set the supplier's Regulatory Compliance Declaration to 'compliant' for these SVHCs).

The CAS numbers published by ECHA for the 125 REACH Candidate List substances which can normally be found in supplied articles are included in the table below. Note that ECHA has not published CAS numbers for some REACH Candidate List Substances. BOMcheck is aligned with the IPC 1752A and IPC 1752B substance category list EUREACH-0125.

REACH Candidate List Substances which can normally be found in supplied articles	CAS number(s) published by ECHA	Threshold
<i>Included in REACH Candidate List on 28 October 2008</i>		
Benzyl butyl phthalate (BBP)	85-68-7	0.1% by weight (1 000 ppm) of any article
Dibutyl phthalate (DBP)	84-74-2	0.1% by weight (1 000 ppm) of any article
Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	0.1% by weight (1 000 ppm) of any article
Hexabromocyclododecane (HBCDD) and all major diastereoisomers	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	0.1% by weight (1 000 ppm) of any article
Shortchain chlorinated paraffins (C10 – C13)	85535-84-8	0.1% by weight (1 000 ppm) of any article
Cobalt dichloride (CoCl ₂)	7646-79-9	0.1% by weight (1 000 ppm) of any article
Diarsenic pentoxide	1303-28-2	0.1% by weight (1 000 ppm) of any article
Diarsenic trioxide	1327-53-3	0.1% by weight (1 000 ppm) of any article
Tributyl tin oxide (TBTO)	56-35-9	0.1% by weight (1 000 ppm) of any article

<i>Included in REACH Candidate List on 13 January 2010</i>		
Tris (2-chloroethyl) phosphate (TCEP)	115-96-8	0.1% by weight (1 000 ppm) of any article
Lead chromate	7758-97-6	0.1% by weight (1 000 ppm) of any article
Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	12656-85-8	0.1% by weight (1 000 ppm) of any article
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2	0.1% by weight (1 000 ppm) of any article
Diisobutyl phthalate (DIBP)	84-69-5	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 18 June 2010</i>		
Disodium tetraborate, anhydrous	1303-96-4, 1330-43-4, 12179-04-3	0.1% by weight (1 000 ppm) of any article
Tetraboron disodium heptaoxide, hydrate	12267-73-1	0.1% by weight (1 000 ppm) of any article
Boric acid	10043-35-3, 11113-50-1	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 20 June 2011</i>		
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 19 December 2011</i>		
2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.1% by weight (1 000 ppm) of any article
N,N-dimethylacetamide	127-19-5	0.1% by weight (1 000 ppm) of any article
Bis(2-methoxyethyl) phthalate	117-82-8	0.1% by weight (1 000 ppm) of any article
Bis(2-methoxyethyl) ether	111-96-6	0.1% by weight (1 000 ppm) of any article
Aluminosilicate Refractory Ceramic Fibres	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Zirconia Aluminosilicate Refractory Ceramic Fibres	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 18 June 2012</i>		
Diboron trioxide	1303-86-2	0.1% by weight (1 000 ppm) of any article
1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.1% by weight (1 000 ppm) of any article

1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 December 2012		
Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	1163-19-5	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.1% by weight (1 000 ppm) of any article
Diisopentylphthalate	605-50-5	0.1% by weight (1 000 ppm) of any article
N-pentyl-isopentylphthalate	776297-69-9	0.1% by weight (1 000 ppm) of any article
Dibutyltin dichloride (DBTC)	683-18-1	0.1% by weight (1 000 ppm) of any article
Lead oxide sulfate	12036-76-9	0.1% by weight (1 000 ppm) of any article
[Phthalato(2-)]dioxotrilead	69011-06-9	0.1% by weight (1 000 ppm) of any article
Dioxobis(stearato)trilead	12578-12-0	0.1% by weight (1 000 ppm) of any article
Fatty acids, C16-18, lead salts	91031-62-8	0.1% by weight (1 000 ppm) of any article
Lead dinitrate	10099-74-8	0.1% by weight (1 000 ppm) of any article
Pentalead tetraoxide sulphate	12065-90-6	0.1% by weight (1 000 ppm) of any article
Sulfurous acid, lead salt, dibasic	62229-08-7	0.1% by weight (1 000 ppm) of any article
Tetralead trioxide sulphate	12202-17-4	0.1% by weight (1 000 ppm) of any article
Trilead dioxide phosphonate	12141-20-7	0.1% by weight (1 000 ppm) of any article
Orange lead (lead tetroxide)	1314-41-6	0.1% by weight (1 000 ppm) of any article
Lead cyanamidate	20837-86-9	0.1% by weight (1 000 ppm) of any article
Pyrochlore, antimony lead yellow	8012-00-8	0.1% by weight (1 000 ppm) of any article
4-Aminoazobenzene	60-09-3	0.1% by weight (1 000 ppm) of any article
1,2-Diethoxyethane	629-14-1	0.1% by weight (1 000 ppm) of any article
Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8	0.1% by weight (1 000 ppm) of any article
N,N-dimethylformamide; dimethyl formamide	68-12-2	0.1% by weight (1 000 ppm) of any article

Lead titanium trioxide	12060-00-3	0.1% by weight (1 000 ppm) of any article
Lead titanium zirconium oxide	12626-81-2	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2013		
4-Nonylphenol, branched and linear, ethoxylated <i>[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]</i>	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	0.1% by weight (1 000 ppm) of any article
Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.1% by weight (1 000 ppm) of any article
Cadmium	7440-43-9	0.1% by weight (1 000 ppm) of any article
Cadmium oxide	1306-19-0	0.1% by weight (1 000 ppm) of any article
Dipentyl phthalate (DPP)	131-18-0	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 December 2013		
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.1% by weight (1 000 ppm) of any article
Trixylyl phosphate	25155-23-1	0.1% by weight (1 000 ppm) of any article
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.1% by weight (1 000 ppm) of any article
Dihexyl phthalate	84-75-3	0.1% by weight (1 000 ppm) of any article
Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.1% by weight (1 000 ppm) of any article
Cadmium sulphide	1306-23-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 June 2014		
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 December 2014		
2-Benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.1% by weight (1 000 ppm) of any article

2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.1% by weight (1 000 ppm) of any article
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.1% by weight (1 000 ppm) of any article
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 June 2015		
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with greater than or equal to 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5, 68648-93-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 December 2015		
Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1, 21049-39-8, 4149-60-4	0.1% by weight (1 000 ppm) of any article
1,3-propanesultone	1120-71-4	0.1% by weight (1 000 ppm) of any article
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.1% by weight (1 000 ppm) of any article
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2016		
Benzo[def]chrysene	50-32-8	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 12 January 2017		
4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.1% by weight (1 000 ppm) of any article
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	3108-42-7, 335-76-2, 3830-45-3	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 7 July 2017		
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 January 2018		
Benz[a]anthracene	56-55-3, 1718-53-2	0.1% by weight (1 000 ppm) of any article
Cadmium hydroxide	21041-95-2	0.1% by weight (1 000 ppm) of any article

Chrysene	218-01-9, 1719-03-5	0.1% by weight (1 000 ppm) of any article
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 27 June 2018</i>		
Benzo[ghi]perylene	191-24-2	0.1% by weight (1 000 ppm) of any article
Octamethylcyclotetrasiloxane (D4)	556-67-2	0.1% by weight (1 000 ppm) of any article
Decamethylcyclopentasiloxane (D5)	541-02-6	0.1% by weight (1 000 ppm) of any article
Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.1% by weight (1 000 ppm) of any article
Terphenyl, hydrogenated	61788-32-7	0.1% by weight (1 000 ppm) of any article
Disodium octaborate	12008-41-2	0.1% by weight (1 000 ppm) of any article
Lead	7439-92-1	0.1% by weight (1 000 ppm) of any article
Dicyclohexyl phthalate (DCHP)	84-61-7	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 15 January 2019</i>		
Benzo[k]fluoranthene	207-08-9	0.1% by weight (1 000 ppm) of any article
Fluoranthene	206-44-0, 93951-69-0	0.1% by weight (1 000 ppm) of any article
Phenanthrene	85-01-8	0.1% by weight (1 000 ppm) of any article
Pyrene	129-00-0, 1718-52-1	0.1% by weight (1 000 ppm) of any article
2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 16 July 2019</i>		
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP)	106599-06-8, 3050-88-2, 26523-78-4, 31631-13-7	0.1% by weight (1 000 ppm) of any article
<i>Included in REACH Candidate List on 16 January 2020</i>		
Diisohexyl phthalate	71850-09-4	0.1% by weight (1 000 ppm) of any article
Perfluorobutane sulfonic acid (PFBS) and its salts	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article

Included in REACH Candidate List on 25 June 2020		
Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 January 2021		
Bis(2-(2-methoxyethoxy)ethyl)ether	143-24-8	0.1% by weight (1 000 ppm) of any article
Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 8 July 2021		
Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17]	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
4,4'-(1-methylpropylidene)bisphenol	77-40-7	0.1% by weight (1 000 ppm) of any article
Orthoboric acid, sodium salt	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 January 2022		
6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	119-47-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 January 2023		
1,1'-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene]	37853-59-1	0.1% by weight (1 000 ppm) of any article
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	79-94-7	0.1% by weight (1 000 ppm) of any article
4,4'-sulphonyldiphenol	80-09-1	0.1% by weight (1 000 ppm) of any article
Barium diboron tetraoxide	13701-59-2	0.1% by weight (1 000 ppm) of any article
Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	26040-51-7	0.1% by weight (1 000 ppm) of any article
Isobutyl 4-hydroxybenzoate	4247-02-3	0.1% by weight (1 000 ppm) of any article
Melamine	108-78-1	0.1% by weight (1 000 ppm) of any article
Perfluoroheptanoic acid and its salts	375-85-9 6130-43-4 21049-36-5 20109-59-5	0.1% by weight (1 000 ppm) of any article
reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article

Included in REACH Candidate List on 14 June 2023		
bis(4-chlorophenyl) sulphone	80-07-9	0.1% by weight (1 000 ppm) of any article
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 23 January 2024		
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-329)	3147-75-9	0.1% by weight (1 000 ppm) of any article
Bumetrizole (UV-326)	3896-11-5	0.1% by weight (1 000 ppm) of any article
Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	-	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 27 June 2024		
Bis(α,α -dimethylbenzyl) peroxide	80-43-3	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 07 November 2024		
Triphenyl phosphate	115-86-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 21 January 2025		
6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	2156592-54-8	0.1% by weight (1 000 ppm) of any article
O,O,O-triphenyl phosphorothioate	597-82-0	0.1% by weight (1 000 ppm) of any article
Octamethyltrisiloxane	107-51-7	0.1% by weight (1 000 ppm) of any article
Perfluamine	338-83-0	0.1% by weight (1 000 ppm) of any article
reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives	192268-65-8	0.1% by weight (1 000 ppm) of any article

REACH substance restrictions (Annex XVII) applicable to supplied articles

BOMcheck enables suppliers to declare against the following restricted substances that can be present above the threshold levels in parts and materials normally found in supplied articles. Note that “No content permitted” means “The chemical substance is not allowed to be present in the material at any concentration level.”

The BOMcheck Regulatory Compliance Declaration tool provides information sheets for each individual substance restrictions. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these restricted substances. BOMcheck is aligned with the IPC 1752A and IPC 1752B substance category list EUREACH-ARTICLE67-2021/1297.

REACH restricted substances which can normally be found in supplied articles	Threshold	Threshold calculation level
Formaldehyde and formaldehyde releasers	The concentration of formaldehyde released must not exceed 0.080 mg/m ³	Part (article)
Lead and its compounds in PVC	0.1% by weight of the PVC material	Material
Sum of perfluorocarboxylic acids containing 9 to 14 carbon atoms	0.000025% by weight (25ppb) of any article	Part (article)
Bisphenol A in thermal paper	0.02% by weight (200 ppm) in thermal paper	Part (article)
Sum of Selected Phthalates Group 1 (DIBP, BBP, DBP, DEHP)	0.1% w/w of plasticised material	Material
Asbestos fibres	No intentionally added content	Part (article)
Dibutyltin (DBT) compounds	0.1% by weight of tin in a material	Part (article)
Monomethyl dibromodiphenyl methane	No intentionally added content	Part (article)
Monomethyl dichlorodiphenyl methane	No intentionally added content	Part (article)
Monomethyl tetrachlorodiphenyl methane	No intentionally added content	Part (article)
Polychlorinated terphenyls (PCTs)	No intentionally added content	Part (article)
1,2,4 Trichlorobenzene	Concentration must be < 0.1% w/w	Part (article)
Dimethyl Fumarate	0.00001% (0.1 ppm) w/w	Part (article)
Tri-substituted organostannic compounds	0.1 % by weight of tin in a material	Part (article)
Tar oils and creosotes	No content permitted in wood	Part (article)
Restrictions which apply to parts used in childcare products and toys		
Benzene	Concentration must be < 0.0005% w/w in toys	Part (article)
Diocetyl tin (DOT) compounds	0.1% by weight of tin in a material	Part (article)
Selected Phthalates Group 2 (DIDP, DINP, DNOP)	0.1% w/w of plasticised material when used in toys and childcare articles which can be placed in the mouth	Material
Any individual PAH compound – toys and childcare articles	0.00005% by weight (0.5 ppm) in plastic or rubber material in toys and childcare articles that come into direct, prolonged or repetitive skin or oral cavity contact	Part (article)
Restrictions which apply to parts containing leather or textiles		
Sum of undecafluorohexanoic acid (PFHxA) and its salts	0.000025% by weight (25ppb) of any material used in restricted applications	Material
Sum of PFHxA-related substances	0.0001% (1000 ppb) of any material used	Material

	in restricted applications	
Diocetyl tin (DOT) compounds	0.1% by weight of tin in a material	Part (article)
Azo colourants containing certain amines	Not permitted in textile and leather articles which may come into direct and prolonged contact with skin	Part (article)
Tri (2,3-dibromo-propyl) phosphate	Not permitted in textile articles which may come into contact with skin	Part (article)
Tris (aziridinyl) phosphin oxide	Not permitted in textile articles which may come into contact with skin	Part (article)
Restrictions which apply to parts which come into contact with skin		
Any individual PAH compound	0.0001% by weight (1 ppm) in plastic or rubber material that come into direct, prolonged or repetitive skin or oral cavity contact	Part (article)
Nickel and nickel alloys	Must not be used in applications with direct and prolonged skin contact and where the rate of nickel release is > 0.5 micro gms per cm ² per week	Part (article)
Restrictions which apply to parts which contain chemical products (liquids, gases, powders)		
Benzene	< 0.1% w/w in any substance or preparation	Part (article)
Nonylphenol and nonylphenol ethoxylates	Concentration must be < 0.1% w/w	Part (article)

Batteries substance restrictions

The following restrictions apply to all batteries. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these restricted substances.

Substances	Maximum concentration in the battery	Threshold calculation level
Cadmium/cadmium compounds	0.001 % by weight (10 ppm) of battery	Part (article)
Mercury/mercury compounds	0.0001% by weight (1 ppm) of battery	Part (article)
Lead/lead compounds	0.004% by weight (40 ppm) of battery	Part (article)
Perchlorates	0.0000006% by weight (6 ppb) of battery	Part (article)

Proposition 65

Screening of the 900 plus substances on the Proposition 65 list has shown that a small subset of substances may be found in components of manufactured products (not defined as a substance or preparation (mixture) under the REACH regulation). Many of these substances are not present in supplied articles and so do not require "safe harbour" warnings and many substances are already regulated under RoHS, REACH, POPs and

Version 8.3, February 2025

other regulations in BOMcheck. The remaining Proposition 65 substances which require additional compliance declarations can be found with detailed chemical guidance to help you assess if they may be found in your parts.

If the finished product includes a supplier part that contains Proposition 65 substance(s) then you need to assess whether the user could be exposed to the part during normal use of the product. If yes, then you should provide an appropriate “safe harbour” warning and communicate the name of one Proposition 65 substance for each endpoint (for example, one carcinogen of the Proposition 65 substance(s) is listed for cancer).

Proposition 65 substances which can normally be found in supplied articles	Threshold	Threshold calculation level
Silicon carbide whiskers	0.1% by weight (1 000 ppm) of any material	Part (article)
Tetrahydrofuran	0.1% by weight (1 000 ppm) of any material	Material
Methyl acrylate	0.1% by weight (1 000 ppm) of any material	Material
Indium tin oxide	0.1% by weight (1 000 ppm) of any material	Material
Lead and Lead Compounds	0.009% (90 ppm) of any material	Material
Bisphenol A (BPA)	0.0003% (3 ppm) of any material	Material
Ethylene Oxide	No intentionally added content	Part (article)
Phthalate plasticisers		
Diisononyl phthalate (DiNP)	No intentionally added content	Part (article)
Di-isodecyl phthalate (DIDP)	No intentionally added content	Part (article)
Di-n-hexyl phthalate (DnHP)	No intentionally added content	Part (article)
Flame retardants and plasticisers		
Tris(1,3-dichloro-2-propyl) Phosphate (TDCPP)	0.0025% by weight (25 ppm) of any material	Part (article)
Tris(2-chloroethyl) Phosphate	0.0025% by weight (25 ppm) of any material	Part (article)
Tris(2,3-dibromopropyl)phosphate	0.0025% by weight (25 ppm) of any material	Part (article)
Flame retardants		
Dimethyl hydrogen phosphite	0.1% by weight (1 000 ppm) of any material	Part (article)
Molybdenum Trioxide	0.1% by weight (1 000 ppm) of any material	Material

Antimony Oxide (Antimony trioxide)	0.1% by weight (1 000 ppm) of any material	Part (article)
Tetrabromobisphenol A	0.1% by weight (1 000 ppm) of any material	Part (article)
2,2-Bis(bromomethyl)-1,3-propanediol	0.1% by weight (1 000 ppm) of any material	Part (article)
Mirex	0.1% by weight (1 000 ppm) of any material	Part (article)
UV protection agents		
Benzophenone	0.1% by weight (1 000 ppm) of any material	Part (article)
Colourants		
Benzidine-based Dyes	0.1% by weight (1 000 ppm) of any material	Part (article)
3,3'-Dimethoxybenzidine-based dyes metabolized to 3,3'-dimethoxybenzidine	0.1% by weight (1 000 ppm) of any material	Part (article)
3,3'-Dimethylbenzidine-based dyes metabolized to 3,3'-dimethylbenzidine	0.1% by weight (1 000 ppm) of any material	Part (article)
D&C Orange No. 17	0.1% by weight (1 000 ppm) of any material	Part (article)
1-Amino-2,4-dibromoanthraquinone	0.1% by weight (1 000 ppm) of any material	Part (article)
1-Amino-2-methylantraquinone	0.1% by weight (1 000 ppm) of any material	Part (article)
Direct Blue 6 (Technical Grade)	0.1% by weight (1 000 ppm) of any material	Part (article)
Direct Brown 95 (Technical Grade)	0.1% by weight (1 000 ppm) of any material	Part (article)
Disperse Blue 1	0.1% by weight (1 000 ppm) of any material	Part (article)
Impurities in extender oils and black colourants		
Naphthalene	0.0001% by weight (1 ppm) of any material	Part (article)
REACH Article 67 substance restrictions which may be found in hardware and electrical and electronic equipment (Regulation 1907/2006)		
Any individual PAH compound	0.0001% by weight (1 ppm) in plastic or rubber material that come into direct, prolonged or repetitive skin or oral cavity contact	Part (article)
Asbestos	No intentionally added content	Part (article)

Azocolourants and azodyes which form certain aromatic amines	Not permitted in textile and leather articles which may come into direct and prolonged contact with skin	Part (article)
Nickel and nickel alloys	Must not be used in applications with direct and prolonged skin contact and where the rate of nickel release is > 0.5 micro gms per cm ² per week	Part (article)
Tar oils and creosotes	No content permitted in wood and wooden materials	Part (article)
RoHS substance restrictions (Directive 2011/65/EU)		
Cadmium/cadmium compounds	0.01% by weight (100 ppm) of homogeneous materials	Material
Hexavalent Chromium	0.1% by weight (1 000 ppm) of homogenous materials	Material
Mercury/Mercury compounds	0.1% by weight (1 000 ppm) of homogenous materials	Material
PBBs	0.1% by weight (1 000 ppm) of homogenous materials	Material
PBDEs	0.1% by weight (1 000 ppm) of homogenous materials	Material
REACH candidate list substances (Regulation 1907/2006)		
Bisphenol S (BPS)	0.1% by weight (1 000 ppm) of any material	Material
Perfluorononanoic acid (PFNA) and its salts	0.1% by weight (1 000 ppm) of any article	Part (article)
DEHP (Di(2-ethylhexyl) phthalate)	0.1% by weight (1 000 ppm) of any article	Part (article)
DBP (Dibutyl phthalate)	0.1% by weight (1 000 ppm) of any article	Part (article)
BBP (Benzylbutyl phthalate)	0.1% by weight (1 000 ppm) of any article	Part (article)
SCCP (Short-chained chlorinated paraffins)	0.1% by weight (1 000 ppm) of any article	Part (article)
Direct Black 38 (Technical Grade)	0.1% by weight (1 000 ppm) of any article	Part (article)
4-Aminoazobenzene	0.1% by weight (1 000 ppm) of any article	Part (article)
Persistent Organic Pollutants Regulation (EU) 2019/1021		
Perfluorooctane sulfonic acid (PFOS) and its salts and transformation and degradation precursors	0.1% by weight (1 000 ppm) of any material	Part (article)
Polychlorinated biphenyls (PCBs)	No intentionally added content	Part (article)
Perfluorooctanoic acid and its salts	0.000025% by weight (25ppb) of any article	Part (article)

Additional Declarable Substance Lists (Additional DSLs)

BOMcheck includes substances which are restricted or declarable in legislation in all parts of the world, including North America, Asia Pacific and Europe. The BOMcheck Steering Group has screened-out substance restrictions or declaration requirements which are not relevant to parts and materials normally found in supplied articles. BOMcheck enables suppliers to declare against the following substances which can be present above the threshold levels in parts and materials normally found in supplied articles. Note that “No content permitted” means “The chemical substance is not allowed to be present in the material at any concentration level”.

The BOMcheck Regulatory Compliance Declaration tool provides information sheets for each individual substance restriction or declaration requirement, including the applicable legislation and information on alternative substances. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these regulated substances.

Per and -poly fluoroalkyl Substances (PFAS)

Substances	Information	Threshold	Threshold calculation level
IEC PFAS list	Contains 615 reference substances with CAS numbers	No intentionally added content	Material
BOMcheck PFAS list	Contains 11,098 reference substances with CAS numbers	No intentionally added content	Material

Persistent Organic Pollutants (POPs) Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants (POPs) is a global treaty aimed at eliminating or restricting the production and use of hazardous chemicals known as POPs. These substances are highly toxic, persist in the environment, bioaccumulate in living organisms, and pose significant risks to human health and ecosystems. Each country or region enforces the Convention through its own legal framework.

Only POPs substances relevant to supplied articles, such as certain industrial chemicals, are included in BOMcheck. POPs identified as pesticides are not included. For more details, please contact us.

Substances	Threshold	Threshold calculation level
Pentachlorophenol (PCP)	No intentionally added content	Part (article)
Polychlorinated and polybrominated dioxins and furans	No intentionally added content	Part (article)
Perfluorooctane sulfonate (PFOS)	No intentionally added content	Part (article)
HBCDD (Hexabromocyclododecane)	0.0075% (75 ppm) by weight in a material	Material
Shortchain chlorinated paraffins (C10 – C13)	0.15% (1 500 ppm) by weight in a material	Part (article)
Polychlorinated biphenyls (PCBs)	No intentionally added content	Part (article)
Polychlorinated naphthalenes (PCNs)	No intentionally added content	Part (article)

Polybrominated diphenyl ethers (PBDEs)	No intentionally added content	Material
Perfluorooctanoic acid and its salts	0.0000025% by weight (25 ppb) of any article	Part (article)
PFOA-related substances	0.0001% (1 ppm) of any article	Part (article)
Perfluorohexane-1-sulphonic acid, its salts and related substances	0.0000025% by weight (25 ppb) of any article	Part (article)
Hexachlorobenzene	0.001% (10 ppm) by weight in a material	Part (article)
Dechlorane Plus	No intentionally added content	Part (article)
UV-328	No intentionally added content	Part (article)

Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h)

The Toxic Substances Control Act (TSCA), under Section 6(h), requires the U.S. Environmental Protection Agency (EPA) to take expedited action on certain chemicals identified as Persistent, Bioaccumulative, and Toxic (PBT). In January 2021, the EPA issued final rules to reduce exposures to five PBT chemicals. The BOMcheck screening has resulted in only 2 of these 5 substances requiring a declaration by suppliers.

Substances	Threshold	Threshold calculation level
Phenol, Isopropylated Phosphate (3:1) (PIP 3:1)	No intentionally added content	Part (article)
Decabromdiphenylether (DecaBDE)	No intentionally added content	Material

Other restricted or declarable substances

BOMcheck includes substances which are restricted or declarable in legislation in all parts of the world, including North America, Asia Pacific and Europe. The BOMcheck Steering Group has screened-out substance restrictions or declaration requirements which are not relevant to parts and materials normally found in supplied articles. BOMcheck enables suppliers to declare against the following substances which can be present above the threshold levels in parts and materials normally found in supplied articles. Note that "No content permitted" means "The chemical substance is not allowed to be present in the material at any concentration level".

The BOMcheck Regulatory Compliance Declaration tool provides information sheets for each individual substance restriction or declaration requirement, including the applicable legislation and information on alternative substances. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these regulated substances.

For a list of legislation covered by this section see <https://docs.bomcheck.com/en/resources/substances.html>.

Substances which can normally be found in supplied articles	Threshold	Threshold calculation level
Cholecalciferol	0.1% by weight (1 000 ppm) of any article	Part (article)

Diisooctyl phthalate (DIOP)	0.1% by weight (1 000 ppm) of any article	Part (article)
Sum of perfluorocarboxylic acids containing 9 to 14 carbon atoms	0.0000025% by weight (25 ppb) of any article	Part (article)
Bisphenol S in thermal paper	0.02% by weight (200 ppm) in thermal paper	Part (article)
Formaldehyde	No intentionally added content in composite wood products or components (plywood, particle board and MDF) and textiles	Part (article)
Radioactive substances	No intentionally added content	Part (article)
Biocides	No intentionally added biocides	Part (article)
Restrictions which apply to parts used in childcare products and toys		
Flame retardant chemicals	0.1% by weight (1 000 ppm) in a material in toys and childcare products	Material
Di-n-pentyl phthalate (DPENP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products	Material
Di-n-hexyl phthalate (DHEXP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products	Material
Dicyclohexyl phthalate (DCHP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products	Material
Diisononyl phthalate (DINP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products	Material
Tris (2-chloroethyl) phosphate (TCEP)	No content permitted in toys and childcare products	Part (article)
Tris(2-chloro-1-methylethyl) phosphate (TCPP)	No content permitted in toys and childcare products	Part (article)
Tris (1,3-dichloro-2-propyl) phosphate (TDCPP)	No content permitted in toys and childcare products	Part (article)
Lead/lead compounds	0.01% w/w in consumer products designed or intended primarily for children 12 years of age or younger	Part (article)
Lead/lead compounds	0.009% w/w in paint and similar surface coatings of toys and other articles intended to be used by children	Part (article)

Mercury	0.001% w/w in paint and similar surface coatings of toys and other articles intended for use by children	Part (article)
Restrictions which apply to parts used in medical devices		
Bisphenol A	Declare if manufactured from raw materials using BPA or derived from BPA, and if used in medical devices and part comes into contact with patient or patient fluids	Part (article)
Latex	No intentionally added content in medical devices	Part (article)
CMR 1A and 1B substances and endocrine disrupting substances	0.1% by weight (1 000ppm) in any material which has invasive contact with the patient, or any material which transports or stores fluids or gases which contact the patient	Material
Restrictions which apply to parts which come into contact with food		
Bisphenol A	No content permitted in products which contact with food	Part (article)
Restrictions which apply to parts which contain chemical products (liquids, gases, powders)		
Ozone depleting substances	No intentionally added content	Part (article)
Fluorinated Greenhouse Gases (PFC, SF6, HFC)	No content permitted	Material
Restrictions which apply to parts which contain textiles		
Flame retardant chemicals	0.1% by weight (1 000 ppm) in a material in textiles	Material
Restrictions which apply to parts which contain printing ink		
Mineral oil aromatic hydrocarbons (MOAH) consisting of 1-7 aromatic cycles	0.1% by weight (1 000 ppm) in the ink	Part (article)
Mineral oil saturated hydrocarbons (MOSH) consisting of 16-35 carbon atoms	0.1% by weight (1 000 ppm) in the ink	Part (article)

Industry restricted and declarable substances

The following substances are restricted by leading OEMs to comply with product safety standards in Germany and to reduce severe environmental or health and safety impacts. Suppliers can check the information pages in the BOMcheck tool to find out which OEMs require their suppliers to comply with particular industry substance restrictions.

Substances which can normally be found in supplied articles	Threshold	Threshold calculation level
Beryllium and Beryllium compounds	0.1% by weight (1 000 ppm) of any material	Material
Rare earth minerals	No intentionally added content	Part (article)
Precious metals	No intentionally added content	Part (article)
Brominated flame retardants (other than PBBs, PBDEs or HBCDD)	Declare if > 0.1% w/w total bromine content from BFRs	Part (article)
Brominated flame retardants (other than PBBs, PBDEs or HBCDD)	Declare if > 0.09% total bromine content from BFRs in printed wiring board laminate	Part (article)
Chlorinated flame retardants	Declare if > 0.1% w/w total chlorine content from CFRs	Part (article)
Chlorinated flame retardants	Declare if > 0.09% total chlorine content from CFRs in printed wiring board laminate	Part (article)
PVC and PVC copolymers	Declare if > 0.1% w/w total chlorine content from PVC	Part (article)
Antimony trioxide in plastic materials	Declare if > 0.1% w/w in plastic parts	Part (article)
Phthalates	Declare if > 0.1% w/w	Part (article)
Restrictions which apply to parts containing leather or textiles		
Alkylphenol and alkylphenol ethoxylates	0.01% by weight (100 ppm) in textile and leather articles	Part (article)
Restrictions which apply to parts used in lamps and lamp ballasts		
Antimony compounds in glass	0.1% w/w in glass in lamps	Part (article)
Arsenic compounds in glass	0.1% w/w in glass in lamps	Part (article)
Polycyclic Aromatic Hydrocarbons (PAH)	0.005% in potting material in electronic or magnetic ballast for lamps	Part (article)
Restrictions which apply to parts which come into contact with skin		
Azo Colourants	30 ppm if part comes into contact with skin	Part (article)
Benzoapyrene in contact with skin	The limits for different applications are provided in the information sheet	Part (article)
Sum of all PAHs	The limits for different applications are provided in the information sheet	Part (article)

2. Packaging restrictions

Packaging Directive 94/62/EC

Substances	Maximum concentration in the supplied packaging
Sum of all heavy metals (Cd, Hg, Cr(VI) and Pb)	0.01% in the supplied packaging

Registration Evaluation Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006 (as amended)

REACH Candidate List substances found in packaging

REACH Article 33 requires all suppliers to inform their customers if the product they supply includes any article which contains any of the substances in the Candidate List in concentrations > 0.1% w/w of the article. An article is a product which has a special shape, surface or design which determines its function to a greater degree than its chemical composition. Please note that this definition of an article may apply to individual components in your product. For further guidance on what is considered an article under the REACH Regulation please refer to the ECHA Guidance published at https://echa.europa.eu/documents/10162/2324906/articles_en.pdf. The REACH regulation also applies to packaging.

Please see the table in section 1 above for a list of screened substances.

REACH Article 67 and other substance restrictions applicable to packaging articles

Substances which can normally be found in packaging articles	Threshold
Arsenic compounds	No intentionally added content
Formaldehyde	0.1% in the supplied packaging
Dimethyl Fumarate	0.00001% (0.1 ppm) w/w
Degradable plastic	No content permitted
Expanded polystyrene (EPS) and other polymeric foam materials (e.g, EPP, EPE, EVA)	No content permitted
Non-recyclable styrenic polymers or copolymers	No content permitted
Printing inks used in packaging	
Mineral oil aromatic hydrocarbons (MOAH) consisting of 1-7 aromatic cycles	0.1% by weight (1 000 ppm) in the ink
Mineral oil saturated hydrocarbons (MOSH) consisting of 16-35 carbon atoms	0.1% by weight (1 000 ppm) in the ink

Industry-restricted and declarable substances

These substances are restricted by leading OEMs to comply with retailer restrictions on PVC in packaging .. Suppliers can check the information pages in the BOMcheck tool to find out which OEMs require their suppliers to comply with particular industry substance restrictions.



Substances that can be found in packaging articles	Maximum concentration of the substance in the supplied packaging
PVC	0.1% in supplied packaging

Appendix A: Exemptions published in Annex III to the RoHS Directive (2011/65/EU) which remain valid for Medical Devices as of February 2025

Number	Description
5(b)	Lead in glass of fluorescent tubes not exceeding 0.2% by weight
6(a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35% lead by weight
6(a)-I	Lead as an alloying element in steel for machining purposes containing up to 0.35% lead by weight and in batch hot dip galvanised steel components containing up to 0.2% lead by weight
6(b)	Lead as an alloying element in aluminum containing up to 0.4% lead by weight
6(b)-I	Lead as an alloying element in aluminium containing up to 0.4% lead by weight, provided it stems from lead-bearing aluminium scrap recycling
6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content of up to 0.4% lead by weight
6(c)	Copper alloy containing up to 4% lead by weight
7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher
8(b)	Cadmium and its compounds electrical contacts
8(b)-I	Cadmium and its compounds in electrical contacts used in: circuit breakers, thermal sensing controls, thermal motor protectors (excluding hermetic thermal motor protectors), AC switches rated at: 6 A and more at 250 V AC and more, or 12 A and more at 125 V AC and more, DC switches rated at 20 A and more at 18 V DC and more, and switches for use at voltage supply frequency greater than or equal to 200 Hz
13(a)	Lead in white glasses used for optical applications
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards
13(b)-I	Lead in ion coloured optical filter glass types
13(b)-II	Cadmium in striking optical filter glass types; excluding applications falling under point 39(a) of this Annex
13(b)-III	Cadmium and lead in glazes used for reflectance standards
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: a semiconductor technology node of 90 nm or larger; a single die of 300 mm ² or larger in any semiconductor technology node; stacked die packages with die of 300 mm ² or larger, or silicon interposers of 300 mm ² or larger
18(b)	Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi ₂ O ₅ :Pb)

18(b)-I	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi ₂ O ₅ :Pb) when used in medical phototherapy equipment
24	Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes
34	Lead in cermet-based trimmer potentiometer elements
39(a)	Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (less than 0.2 microgram Cd per mm ² of display screen area)
39(b)	Cadmium in downshifting semiconductor nanocrystal quantum dots directly deposited on LED semiconductor chips for use in display and projection applications (< 5 µg Cd per mm ² of light emitting LED chip surface) with a maximum amount per device of 1 mg

Appendix B: Exemptions published in Annex IV to the RoHS Directive (2011/65/EU) which remain valid for Medical Devices as of February 2025

Number	Description
1	Lead, cadmium and mercury in detectors for ionising radiation
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.
2	Lead bearings in X-ray tubes.
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
5	Lead in shielding for ionising radiation.
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.
13	Lead in counterweights.
14	Lead in single crystal piezoelectric materials for ultrasonic transducers.
15	Lead in solders for bonding to ultrasonic transducers.
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
20	Cadmium in X-ray measurement filters.
26	Lead in the following applications that are used durably at a temperature below $-20\text{ }^{\circ}\text{C}$ 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 $-150\text{ }^{\circ}\text{C}$.
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 isocenter 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. (c) MRI non-integrated coils, for which the Declaration of Conformity of this model is issued for the first time before 23 September 2022, or (d) MRI devices including integrated coils, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, for which the Declaration of Conformity is issued for the first time before 30 June 2024
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.
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.
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.

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.
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 mm ² ; (iii) a multiplication factor larger than 1.3×10^3 . (c) a response time shorter than 5 ns for detecting electrons or ions; (d) a sample detection area larger than 314 mm ² for detecting electrons or ions; (e) a multiplication factor larger than 4.0×10^7 . 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.
42	Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (greater than 50 MHz) modes of operation.
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
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.
48	Lead in bismuth strontium calcium copper oxide (BSCCO) superconductor cables and wires and lead in electrical connections to these wires
49	Mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and pressures over 1 000 bar