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|  Corporate Standard February 2020 |
|  |  | Environmental protection and industrial safetyRestricted use of substances | **CZ-Norm****5020** |
|  Replacement for issue July 2019 |

1. Scope of application, purpose

This standard is aimed to

1. support the observance of **environmental protection** and **occupational safety** requirements in the **handling of substances, mixtures and products** not only during production (process-related), but also in the **recycling and disposal** of intermediate and final products, and to ensure compliance with the **applicable legislation**.

2. ensure compliance with existing legal restrictions of the use of substances and mixtures in products made and launched by ZEISS (product-related).

The substance list (substance declaration list and blacklist of Carl Zeiss AG) is also aimed to obligate all ZEISS employees **not** to use restricted substances, mixtures and products and to replace them with substances, mixtures and products that are **less hazardous** according to the relevant specification documents (drawings, work schedules, SOPs, WIs, etc.).

The substance list is available as an Excel file on the ZEISS Management System SharePoint Environmental Protection CZN 5020 leaflet and CZN 5021 leaflet.This Excel file can be completed either electronically or on the printout. Furthermore, a PDF-file is available on the ZEISS Intranet as Leaflet 1 for CZN 5020.

The stipulations of this standard apply to all

* **substances and mixtures**
* **substances and mixtures in products**
* **products** (e. g. complete instruments, assemblies, components, semi-finished products)
* **packaging materials**

This standard draws the attention of all suppliers to their responsibility concerning compliance with the applicable laws and regulations on environmental protection and occupational safety.

1. Terms

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| **Substances** are chemical elements and their compounds in the natural state or obtained by any other production process, including any required additives and any impurity deriving from the process used. |

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| **Mixtures** are blends or solutions consisting of two or more substances. |

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| **Products** are substances or mixtures which, in the course of their manufacture, are given a specific structure, surface or shape which determines their function to a higher degree than their chemical composition as such or in composite form. |

1. Responsibilities
* The **environmental protection officers** of the locations are responsible for the **update** of this standard.
* The **purchase (procurement)** department is responsible for **forwarding** this standard to the **suppliers**.
* The **development and design departments** (persons responsible for the product) are responsible for verification of conformity of substances, mixtures and products with the described requirements of the standards.
* The **production or process development departments** (persons responsible for the process) are responsible for compliance of all **operating supplies** with this standard.

Each ZEISS employee constantly using any **substance, preparation, raw materials / auxiliary materials / operating supplies or material** (see CZN 2160 for definitions) in processes and/or production and applying for the required material number must **verify** compliance with this standard and procure the respective data according to the substance list. **Hazardous substances** always require the latest **safety data sheet** and a **technical description** from the supplier.

All **suppliers** are obliged to comply with the **duty of declaration for substances**, **observe** or fall below **the maximum permissible concentration** and not to use **banned substances**.

If suppliers have an exceptional permission (statutory/official) for the production and launch of controlled substances, mixtures and products, this must be verified vis-à-vis ZEISS.

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**4 Restricted use of substances**

4.1 **General substance bans and restrictions**

Substances and mixtures as well as substances and mixtures in products to be supplied to ZEISS must not contain any of the following ingredients, unless an exceptional permission in the form of order documents is available for these substances and of course all applicable statutory provisions must be complied with:

4.1.1 Carcinogenic ingredients as per EU classification under the Chemicals Act, Cat. 1A, 1B and 2.

4.1.2 Ingredients endangering reproduction as per EU classification under the Chemicals Act, Cat. 1A, 1B and 2.

4.1.3 Mutagenic ingredients as per EU classification under the Chemicals Act, Cat. 1A, 1B and 2.

4.1.4 Very toxic or toxic ingredients as per EU classification under the Chemicals Act, Cat. 1, 2 and 3.

4.1.5 Ingredients depleting the ozone layer covered by Council Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer as well as Class I and Class II substances according to the US Clean Air Act. Class I of this Act includes chlorofluorocarbons (CFCs), halons, bromomethane, carbon tetrachloride and 1.1.1-trichlorethane; Class II includes partly halogenated chlorofluorocarbons.

4.1.6 Asbestos (e. g. actinolite, amosite, anthophyllite, chrysotile, crosidolite, tremolite).

4.1.7 Radioactive substances, mixtures and products which can emit alpha, beta or gamma radiation.

4.1.8 Substances or materials which degas gaseous formaldehyde at >0.1 ml/m3.

4.1.9 Materials or products containing harmful organisms, e. g. insects, worms and fungi.

4.1.10 **All** substances listed in Annex XVII (RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE

MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES) of the REACH regulation 1907/2006 in its newest version (with the sole exemption of the allowed maximum concentrations)

4.1.11 **All** substances listed in Annex I of the POP Regulation 2019/1021/EC as such or substances in mixtures and articles (except for the maximum permitted concentrations specified therein)

4.1.12

All substances listed in Annex I No. 10.4.1 of the Medical Devices Regulation 2017/745/EC as such or substances in mixtures and articles (except for the maximum permitted concentrations specified there).

The regulated substances of EU Regulation 2017/745/EC are in particular carcinogenic, mutagenic or toxic to reproduction ("CMR substances") of categories 1A and 1B according to CLP Regulation 1272/2008/EC as well as substances with endocrine disrupting properties (i.e. substances that may damage health by altering the endocrine system).

The Supplier must provide proof of the absence of these substances by means of a chemical analysis or by proving the chemical composition of the base materials with the supplementary declaration that no prohibited substances can be introduced due to the way it is processed, nor must chemical processes be initiated which make the material critical with regard to No. 10.4.1 from Annex I of the EU Medical Devices Regulation if the Supplier delivers to **Carl Zeiss Meditec AG or its subsidiaries**. If the supplier does not meet these requirements, the usability of the substance to be purchased must be conclusively checked as part of a risk-based approach.

Furthermore, ingredients may only be available in the concentrations specified in the attached “Substance list”. Explicitly banned ingredients must not be part of the formula and not be contained in the used formula components either. The duty to submit a declaration for specific substance ingredients must also be complied with.

The above restrictions can be removed in exceptional cases. These exemptions shall be limited in time until state-of-the-art solutions have been found.

For hazardous ingredients in substances and mixtures, the declaration limits given in the safety data sheet applies, unless lower limit values are specified in the substance list.

**4.2 Evidence of compliance with substance bans by suppliers**

In the case of deliveries of substances and mixtures, proof of compliance with the substance bans must be provided by the supplier via the safety data sheets in accordance with Art. 31 of REACH Regulation 1907/2006/EC and the completed declaration lists for ZEISS Standard 5020. Instead of the completed declaration list for substances and mixtures, another suitable declaration of conformity of the supplier to ZEISS Standard 5020 is also permissible.

Proof of compliance with the substance bans must be provided for the supply of substances and mixtures in articles (e.g. possible pollutants in plastic articles) via a suitable declaration of conformity from the supplier to the ZEISS standard 5020 as well as measurement protocols from independent, accredited testing laboratories.

**4.3 Evidence of compliance with substance bans by ZEISS**

In the ZEISS units, delivered substances and mixtures as well as substances and mixtures in products are to be subject to incoming goods inspection and batch control in accordance with the quality control plan of the respective unit.

In the case of substances and mixtures in delivered products (e.g. possible pollutants in plastic articles), the ZEISS units shall carry out initial sample tests and ongoing batch checks by means of analyses in independent, accredited testing laboratories. These tests shall be repeated in particular if a change of supplier is carried out.

For products, first priority in the sense of a risk assessment must be given to tests for compliance with substance restrictions to those product components that

- have skin contact with the consumer and/or

- have eye contact with the consumer and/or

- the consumer may be able to inhale and/or

- can be put in children’s mouths.

## 5 Obligation to declare ingredients

Substances and mixtures as well as substances and mixtures in products may contain hazardous ingredients only if these have been declared in the safety data sheet.

With the respective first delivery, the supplier must specify the other ingredients contained in the substance lists which are subject to declaration.

Ingredients depleting the ozone layer must be specified if the substances, mixtures or products to be delivered to ZEISS contain these ingredients (or were used in its production; cf. Chapter 7 of the general Terms and Conditions of Purchase of the Carl Zeiss Group).

The ingredients of metal alloys are considered as declared if they are listed in a national or international standard (e. g. DIN, EN, ISO) or in purchase specifications agreed between ZEISS and the manufacturer and if their limit values have been defined.

Ingredients in products subject to statutory control or control by ZEISS must be declared in the substance lists.

**6 Specific demands on product groups**

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| **Product-related substances**  | **Process-specific substances** |
| Metallic alloys | Cooling lubricants and additives |
| Glass types, monocrystals, glass ceramics and ceramics | Dyes and lacquers |
| Plastic materials (polymers) | Oils and lubricants |
| Batteries | Anticorrosives |
| Adhesives (cured) | Cleaning agents and solvents |
| Coatings | Polishing agents |
| Oils and lubricants | Metal finishing chemicals |
| Cooling agents | Evaporation substances  |
| Gases | Gases |
| Electrical and electronic components | Adhesives |
| Modules containing metal, glass, plastic, electrical/electronic components, etc. | Laboratory chemicals |
| Packaging materials |  |

6.1 Labeling of medical devices with plastic parts

Contained in medical devices that contain natural rubber or natural rubber latex, the symbols may be used on the medical device itself, on its packaging or in the associated documentation.

Excerpt from ISO 15223-1:







7 Comments and exemptions

Note: The official RoHS exemption numbers [#..] according to RoHS 2011/65/EC (Annex III) are specified in brackets.

**7.1 Lead, RoHS-recast 2011/65/EC substance restrictions**

**7.1.1 Limit value**

0.1 weight percent Pb per homogeneous material

**7.1.2 Exemptions:**

[#5a] Lead in glass of cathode ray tubes

[#5b] Lead in glass of fluorescent tubes not exceeding 0,2% by weight

[#6a] Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35% lead by weight. Expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#6a.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. Expires on 21 July 2021 for categories 1-7 and 10.

[#6b] Lead as an alloying element in aluminium containing up to 0,4% lead by weight. Expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,
* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#6b.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. Expires on 21 July 2021 for categories 1-7 and 10.

[#6b.II] Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4% by weight. Expires on 18 May 2021 for categories 1-7 and 10.

[#6c] Copper alloy containing up to 4% lead by weight. Expires on:

* 21 July 2021 for categories 1-7 and 10,
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,
* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#7a] Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead). Applies to categories 1-7 and 10 (except applications, covered by point 24 of this Annex) and expires on 21 July 2021. For categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments expires on 21 July 2021. For category 8 in vitro diagnostic medical devices expires on 21 July 2023. For category 9 industrial monitoring and control instruments and for category 11 expires on 21 July 2024.

[#7b] Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission and network management for telecommunication

[#7c.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. Applies to categories 1-7 and 10 (except applications covered under point 34) and expires on 21 July 2021. For categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments expires on 21 July 2021. For category 8 in vitro diagnostic medical devices expires on 21 July 2023. For category 9 industrial monitoring and control instruments, and for category 11 expires on 21 July 2024.

[#7c.II] Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher. Does not apply to applications covered by point 7(c)-I and 7(c)-IV of this Annex. Expires on:

* 21 July 2021 for categories 1-7 and 10;
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#7c.III] Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC (expires on 01.01.2013 and after that date may be used in spare parts for EEE placed on the market before 01.01.2013)

[#7c.IV] Lead in PZT based dielectric ceramic materials for capacitors which are part of integrated circuits or discrete semiconductors. Expires on:

* 21 July 2021 for categories 1-7 and 10
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#9b] Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications. Applies to categories 8, 9 and 11; expires on:

* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11,
* 21 July 2021 for other subcategories of categories 8 and 9.

[#9b.I] Lead in bearing shells and bushes for refrigerant-containing hermetic scroll compressors with a stated electrical power input equal or below 9 kW for heating, ventilation, air conditioning and refrigeration (HVACR) applications. Applies to category 1; expires on 21 July 2019.

[#11a] Lead used in C-press compliant pin connector systems (may be used in spare parts for EEE placed on the market before 24 September 2010)

[#11b] Lead used in other than C-press compliant pin connector systems (expires on 01.01.2013 and after that date may be used in spare parts for EEE placed on the market before 01.01.2013)

[#12] Lead as a coating material for the thermal conduction module C-ring (may be used in spare parts for EEE placed on the market before 24 September 2010)

[#13a] Lead in white glasses used for optical applications. Applies to all categories; expires on:

* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;
* 21 July 2021 for all other categories and subcategories.

[#13b] Cadmium and lead in filter glasses and glasses used for reflectance standards. Applies to categories 8, 9 and 11; expires on:

* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;
* 21 July 2021 for other subcategories of categories 8 and 9.

[#13b.I] Lead in ion coloured optical filter glass types. Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10.

[#13b.III] Cadmium and lead in glazes used for reflectance standards. Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10.

 #14] Lead in solders consisting of more than two elements for the connection between pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight (expired on 01.01.2011 and after that date may be used in spare parts for EEE placed on the market before 01.01.2011)

[#15] Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages. Applies to categories 8, 9 and 11 and expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#15a] 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 mm² or larger in any semiconductor technology node;
* Stacked die packages with die of 300 mm² or larger, or silicon interposers of 300 mm² or larger.

Applies to category 1 to 7 and 10 and expires on 21 July 2021.

[#16] Lead in linear incandescent lamps with silicate coated tubes (expires on 01.09.2013)

[#17] Lead halide as radiant agent in high intensity discharge (HID) lamps used for professional reprography applications

[#18a] Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ((Sr, Ba)2MgSi2O7:Pb) (expired on 01.01.2011)

[#18b] 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 (BaSi2O5:Pb). Expires on:

* 21 July 2021 for categories 1-7 and 10;
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#18b.I] Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb) when used in medical phototherapy equipment. Applies to categories 5 and 8, excluding applications covered by entry 34 of Annex IV, and expires on 21 July 2021.

[#19] Lead with PbBiSn-Hg and PbInHg-Pb in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL) (expired on 01.06.201)

[#20] Lead oxide on glass used for bonding front and rear substrates of fluorescent lamps used for Liquid Crystal Displays (LCDs) (expired on 01.06.2011)

[#21] Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses. Applies to categories 8, 9 and 11 and expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#21c] Lead in printing inks for the application of enamels on other than borosilicate glasses. Applies to categories 1 to 7 and 10 and expires on 21 July 2021.

[#23] Lead in finishes of fine pitch components other than connectors with a pitch of 0,65 mm or less (may be used in spare parts or EEE placed on the market before 24.09.2010)

[#24] Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors. Expires on:

* 21 July 2021 for categories 1-7 and 10,
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,
* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#25] Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring

[#26] Lead oxide in the glass envelope of black light blue lamps (expired on 01.06.2011)

[#27] Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers (expired on 24.09.2010)

[#29] Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC. Expires on:

* 21 July 2021 for categories 1-7 and 10;
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#31] Lead in soldering materials in mercury free flat fluorescent lamps (which e. g. are used for liquid crystal displays, design or industrial lighting)

[#32] Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes. Expires on:

* 21 July 2021 for categories 1-7 and 10,
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,
* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#33] Lead in solders for the soldering of thin copper wires of 100 μm diameter and less in power transformers

[#34] Lead in cermet-based trimmer potentiometer elements. Applies to all categories; expires on:

* 21 July 2021 for categories 1-7 and 10,
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,
* 21 July 2023 for category 8 in vitro diagnostic medical devices,
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#37] Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body. Expires on:

* 21 July 2021 for categories 1-7 and 10;
* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#41] Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (\* ) Expires on 31 December 2018.
(\*) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1). (Expires on 31 December 2018).

[#42] Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment:

* with engine total displacement >= 15 litres;

or

* with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications. Applies to category 11, excluding applications covered by entry 6(c) of this Annex. Expires on 21 July 2024.

**7.2 Cadmium, RoHS-recast 2011/65/EC substance restrictions**

**7.2.1 Limit value**

0.01 weight percent Cd per homogeneous material

**7.2.2 Exemptions:**

[#8a] Cadmium and is compounds in one shot pellet type thermal cut-offs (expires on 01.01.2012 and after that date may be used in spare parts for EEE placed on the market before 01.01.2012)

[#8b] Cadmium and its compounds in electrical contacts. Applies to categories 8, 9 and 11 and expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#8b.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 >= 200 Hz.

[#13b] Cadmium and lead in filter glasses and glasses used for reflectance standards. Applies to categories 8, 9 and 11; expires on:

* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;
* 21 July 2021 for other subcategories of categories 8 and 9.

[#13b.II] Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex. Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10.

[#13b.III] Cadmium and lead in glazes used for reflectance standards. Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10.

[#21] Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses. Applies to categories 8, 9 and 11 and expires on:

* 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
* 21 July 2023 for category 8 in vitro diagnostic medical devices;
* 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

[#21a] Cadmium when used in colour printed glass to provide filtering functions, used as a component in lighting applications installed in displays and control panels of EEE. Applies to categories 1 to 7 and 10 except applications covered by entry 21b or entry 39 and expires on 21 July 2021.

[#21b] Cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses. Applies to categories 1 to 7 and 10 except applications covered by entry 21a or 39 and expires on 21 July 2021.

[#30] Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB(A) and more

[#38] Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide

[#39] Cadmium in colour-converting II-VI LEDs (< 10 µg Cd per mm² of light-emitting area) for use in solid-state illumination or display systems (expires on 1 July 2014)7.

[#39a] Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (<0,2 µg Cd per mm² of display screen area). Expires for all categories on [two years after the publication of the Delegated Directive in the Official Journal].

[#40] Cadmium in photoresistors for analogue optocouplers applied in professional audio equipment, Expires on 31 December 2013

**7.3 Chromium (VI), RoHS-recast 2011/65/EC substance restrictions**

**7.3.1 Limit value**

0.1 weight percent Cr(VI) per homogeneous material

**7.3.2 Exemptions:**

[#9] Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75% by weight in the cooling solution

**7.4 Mercury, RoHS-recast 2011/65/EC substance restrictions**

**7.4.1 Limit value**

0.1 weight percent Hg per homogeneous material

**7.4.2 Exemptions**

[#1] Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):

[#1a] For general lighting purposes < 30 W: 5 mg (expires on 31.12.2011; 3,5 mg may be used per burner after 31.12.2011 until 31.12.2012; 2,5 mg shall be used per burner after 31.12.2012)

[#1b] For general lighting purposes ≥ 30 W und < 50 W: 5 mg (expires on 31.12.2011 ab; 3,5 mg may be used per burner after 31.12.2011)

[#1c] For general lighting purposes ≥ 50 W und < 150 W: 5 mg

[#1d] For general lighting purposes ≥ 150 W: 15 mg

[#1e] For general lighting purposes with circular or square structural shape and tube diameter ≤ 17 mm (no limitation of use until 31.12.2011; 7 mg may be used per burner after 31.12.2011)

[#1f] For special purpose: 5 mg

[#1g] For general lighting purposes < 30 W with a lifetime equal or above 20 000 h: 3,5 mg; expires on 31 December 2017

[#2a] Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):

[#2a.I] Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e. g. T2): 5 mg (expires on 31.12.2011; 4 mg may be used per lamp after 31.12.2011)

[#2a.II] Tri-band phosphor with normal lifetime and a tube diameter ≥ 9 mm und ≤ 17 mm (e. g. T5): 5 mg (expires on 31.12.2011; 3 mg may be used per lamp after 31.12.2011)

[#2a.III] Tri-band phosphor with normal lifetime and a tube diameter ≥ 17 mm und ≤ 28 mm (e. g. T8): 5 mg (expires on 31.12.2011; 3,5 mg may be used per lamp after 31.12.2012)

[#2a.IV] Tri-band phosphor with normal lifetime and a tube diameter > 28mm (e. g. T12): 5 mg (expires on 31.12.2012; 3,5 mg may be used per lamp after 31.12.2012)

[#2a.V] Tri-band phosphor with long lifetime (≥ 25.000 h): 8 mg (expires on 31.12.2011; 5 mg may be used per lamp after 31.12.2011)

[#2b] Mercury in other fluorescent lamps not exceeding (per lamp):

[#2b.I] Linear halophosphate lamps with tube > 28 mm (e. g. T10 und T12): 10 mg (expires on 13.04.2012)

[#2b.II] Non-linear halophosphate lamps (all diameters): 15 mg (expires on 13.04.2016)

[#2b.III] Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e. g. T9) (no limitation of use until 31.12.2011; 15 mg may be used per lamp after 31.12.2011)

[#2b.IV] Lamps for other general lighting and special purposes ) e. g. induction lamps) (no limitation of use until 31.12.2011; 15 mg may be used per lamp after 31.12.2011)

[#3] Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp):

[#3a] Short length (≤ 500 mm) (no limitation of use until 31.12.2011; 3,5 mg may be used per lamp after 31.12.2011)

[#3b] Medium length (> 500 mm und ≤ 1500 mm) (no limitation of use until 31.12.2011; 5 mg may be used per lamp after 31.12.2011)

[#3c] Long length (> 1500 mm) (no limitation of use until 31.12.2011; 13 mg may be used per lamp after 31.12.2011)

[#4a] Mercury in other low pressure discharge lamps (per lamp) (no limitation of use until 31.12.2011; 15 mg may be used per lamp after 31.12.2011)

[#4b] Mercury in High Pressure Dosium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60:

[#4b.I] P ≤ 155 W (no limitation of use until 31.12.2011; 30 mg may be used per burner after 31.12.2011)

[#4b.II] 155 W < P ≤ 405 W (no limitation of use until 31.12.2011; 40 mg may be used per burner after 31.12.2011)

[#4b.III] P > 405 W (no limitation of use until 31.12.2011; 40 mg may be used per burner after 31.12.2011)

[#4c] Mercury in other High Pressure Dosium (vapour) lamps for general lighting purposes not exceeding (per burner):

[#4c.I] P ≤ 155 W (no limitation of use until 31.12.2011; 25 mg may be used per burner after 31.12.2011)

[#4c.II] 155 W < P ≤ 405 W (no limitation of use until 31.12.2011; 30 mg may be used per burner after 31.12.2011)

[#4c.III] P > 405 W (no limitation of use until 31.12.2011; 40 mg may be used per burner after 31.12.2011)

[#4d] Mercury in High Pressure Mercury (vapour) lamps (HPMV) (expires on 15.04.2015)

[#4e] Mercury in Metal Halide lamps (MH)

[#4f] Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex

[#4g] Mercury in hand crafted luminous discharge tubes used for signs, decorative or architectural and specialist lighting and light-artwork, where the mercury content shall be limited as follows: (a) 20 mg per electrode pair + 0,3 mg per tube length in cm, but not more than 80 mg, for outdoor applications and indoor applications exposed to temperatures below 20 °C; (b) 15 mg per electrode pair + 0,24 mg per tube length in cm, but not more than 80 mg, for all other indoor applications. Expires on 31 December 2018.

[#36] Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display (expired on 01.07.2010)

**7.5 Polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), RoHS-recast 2011/65/EC substance restrictions**

**7.5.1 Limit value**

0.1 weight percent PBBs and PBDEs per homogeneous material

**7.6 Plasticizers according to delegated directive (EU) 2015/863 to RoHS-recast 2011/65/EG**

**7.6.1 Limit value**

0,1 weight percent Di(2-ethylhexyl)phthalat (DEHP) , Butylbenzylphthalat (BBP) , Dibutylphthalat (DBP) and Diisobutylphthalat (DIBP) per homogeneous material

**7.7 Applications exempted from the substance restrictions specific to medical devices and monitoring and control instruments**

Note: The official RoHS exemption numbers [#..] according to RoHS 2011/65/EC (**Annex IV**) are specified in brackets.

**7.7.1 Equipment utilising or detecting ionising radiation**

[#1] Lead, cadmium and mercury in detectors for ionising radiation, expires on 21 July 2021

[#2] Lead bearings in x-ray tubes , expires on 21 July 2021

[#3] Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate, expires on 21 July 2021

[#4] Lead in 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, expires on 21 July 2021

[#5] Lead in shielding for ionising radiation, expires on 21 July 2021

[#6] Lead in x-ray test objects, expires on 21 July 2021

[#7] Lead stearate x-ray diffraction crystals, expires on 21 July 2021

[#8] Radioactive cadmium isotope source portable x-ray fluorescence spectrometers, expires on 21 July 2021

**7.7.2 Sensors, detectors and electrodes**

[#1a] Lead and cadmium in ion selective electrodes including glass of pH electrode, expires on 21 July 2021

[#1b] Lead anodes in electrochemical oxygen sensors, expires on 21 July 2021

[#1c] Lead, cadmium and mercury in infra-red light detectors, expires on 21 July 2021

[#1d] Mercury in reference electrodes: low chloride mercury chloride, mercury sulfate and mercury oxide, expires on 21 July 2021

**7.7.3 Others**

[#9] Cadmium in helium-cadmium lasers, expires on 21 July 2021

[#10] Lead and cadmium in atomic absorption spectroscopy lamps, expires on 21 July 2021

[#11] Lead in alloys as a superconductor and thermal conductor in MRI, expires on 21 July 2021

[#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

[#13] Lead in counterweights, expires on 21 July 2021

[#14] Lead in single crystal piezoelectric materials for ultrasonic transducers, expires on 21 July 2021

[#15] Lead in solders for bonding to ultrasonic transducers, expires on 21 July 2021

[#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, expires on 21 July 2021

[#17] Lead in solders in portable emergency defibrillators, expires on 21 July 2021

[#18] Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm, expires on 21 July 2021

[#19] Lead in Liquid crystal on silicon (LCoS) displays, expires on 21 July 2021

[#20] Cadmium in X-ray measurement filters, expires on 21 July 2021

[#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

[#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

[#23] Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation, expires on 30 June 2021

[#24] Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers, expires 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, expires on 30 June 2021.

[#26] Lead in the following applications that are used durably at a temperature below -20 °C under normal operating and storage conditions:

1. solders on printed circuit boards;
2. Termination coatings of electrical and electronic components and coatings of printed circuit boards;
3. Solders for connecting wires and cables;
4. 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.

[#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.

[#28] Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards, expires 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, expires on 30 June 2021.

[#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.

[#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:

* 21 July 2021 for the use in medical devices other than in vitro diagnostic;
* 21 July 2023 for the use in in vitro diagnostic medical devices;
* 21 July 2024 for the use in electron microscopes and their accessories.

[#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

[#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

[#34] Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi 2 O 5 :Pb) phosphors, expires on 22 July 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 Expires on 21 July 2024.

[#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.

[#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.

[#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.

[#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.

[#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.’ 20.5.2014 L 148/73 Official Journal of the European Union EN.

[#41] Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors hich 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.

[#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.

[#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.

**Applicable documents**

When referring to legal texts, the latest versions must be used.

- REACH regulation 1907/2006/EC

- CLP regulation 1272/2008/EC

- POP regulation 2019/1021/EG

- Directive 2012/19/EC on waste electrical and electronic equipment (WEEE-recast).

* Directive 2011/65/EC governing the restriction of hazardous substances in electrical and electronic equipment (RoHS-recast with revision of appendices III and IV by November 15, 2017).
* Commission delegated directive (EU) 2017/2102 of 15 November 2017 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances
* Medical Device Directive 2017/745/EG

- Chemicals Act (ChemG)

- Ordinance on Hazardous Substances (GefStoffV)

- Chemicals Prohibitions Ordinance (ChemVerbotsV)

- Chemicals / ozone layer directive

- Packaging Ordinance (VerpackV)

- Radiation Protection Ordinance (StrlSchV)

- X-ray Ordinance (RöV)

- Electrical and Electronic Equipment Act (ElektroG)

- Electrical and Electronic Equipment Ordinance (ElektroStoffV)

- German regulation TRGS 611, Restrictions on the use of water-miscible or water-mixed cooling lubricants whose employment can result in the formation of N-nitrosamines (for information purposes only)

- Form “Supplier’s declaration about banned substances and substances subject to the duty of declaration in mixtures, materials, products and packaging material"

- Leaflet 1 for CZN 5020, “Substance declaration list and blacklist of Carl Zeiss AG”

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

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Changes

The following changes have been made to the July 2019 issue:

1. In Section Nr. 4.1.12 introduced (Consideration of Substance Requirements from the EU Medical Device Directive)