Schützinger GmbH · Postfach 810569 · 70522 Stuttgart

Conversion to lead-free in medical technology:
Exemption reinstated

Stuttgart, January 2022

Dear Sir or Madam,

In our information letter of July 2021 (copy attached to this letter), we informed you that exemption 6c for our products in Category 8 - medical devices (other than in vitro) will not be renewed and will expire on 21 July 2021. Thereafter, a transitional period of 12 months will apply during which the products may continue to be placed on the market.

At the moment, there is no fully adequate substitute for the standard brass CuZn39Pb3 and the alternative materials are either more expensive, difficult to obtain, worse to process or have different technical properties and are thus not always suitable as 1:1 replacement.

Therefore, a coalition of companies (Umbrella Industrial Project) has been fighting for many years to have exemption 6c - and many other exemptions - further extended.
All EU countries can request an extension in Brussels. The Öko-Institut e.V. has submitted a 235-page report for Germany, requesting that all exemptions be extended until 21.07.2026 (an extension is only possible for a maximum of 5 years).

Consequence: Until the EU Commission has decided on a further extension, a lead content of up to 4% will continue to be permitted in all categories. When this decision will be taken is currently not foreseeable.

Our recommendation: Products that we have already converted together or that are in the process of conversion should remain or be converted. Lead-free will come sooner or later. If you want to convert additional products, we would be happy to accompany you in this process. Please do not hesitate to contact us!

We will keep up with this topic in our usual reliable manner and inform you about changes.
In case of any questions, please do not hesitate to contact us!

Yours sincerely from Stuttgart,

Bernhard Schützinger
Medical product consultant

Holger Papendick
Medical product consultant

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Conversion to lead-free in medical technology:
Exemption not renewed and expires on July 21th, 2021

Stuttgart, July 2021

Dear Sir or Madam,

With our products we are subject to the EU Directive 2011/65/EU (RoHS II) on the limitation of hazardous substances in electronic equipment, as well as the Delegated Directive 2015/863/EU. The EU Directive 2011/65/EU restricts the use of certain hazardous substances in electrical and electronic equipment. It regulates the use and placing on the market of hazardous substances in electrical equipment and electronic components.

The categories of electrical and electronic equipment covered by this Directive are specified in Annex I as follows:

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment
6. Electrical and electronic tools
7. Toys, leisure and sports equipment
8. **Medical devices**
9. Monitoring and control instruments including industrial monitoring and control instruments
10. Automatic dispensers
11. **Other electrical and electronic equipment not covered by any of the categories above**

The following substances are subject to restrictions by maximum permissible concentrations in homogeneous materials in percent by weight:

- Cadmium (0.01 %)
- **Lead (0.1 %)**
- Mercury (0.1 %)
- Hexavalent chromium (0.1 %)
- Polybrominated biphenyls (PBB) (0.1 %)
- Polybrominated diphenyl ethers (PBDE) (0.1 %)

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Our products belong to the categories 8 and 11 of this Directive. The brass used in the majority of our products has a lead content of approx. 3 % in the metal part.
However, exemption 6c listed in Annex III of the Directive, for uses exempted from the restriction, has allowed us to use lead in copper alloys with a lead content of up to 4% by mass.

As the ECHA-European Chemicals Agency published on its homepage on 22 April this year, this exemption for category 11 and thus for our standard products will be extended until 21 July 2024.

We would like to inform you that this exemption for category 8 - Medical devices (except in vitro) will not be extended and will expire on 21 July 2021. However, there is a transitional period of 12 months during which the products may continue to be placed on the market.

If you have any questions, please do not hesitate to contact us.

Yours sincerely from Stuttgart,

Bernhard Schützinger
Medical product consultant

Holger Papendick
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