

Schützing GmbH · Postfach 81 05 69 · 70522 Stuttgart

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 %)

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 Schützing
Medical product consultant

Holger Papendick
Medical product consultant