

Support for the extension of the exemption Annex III, Exemption 6(c) **The Umbrella Project**

1. Questions for stakeholders of relevance to all exemptions

1. The applicant has requested the renewal of an exemption currently listed in RoHS Annex III (see exemption specific page accessible through the links above):

a. Do you agree with the scope of the exemption as proposed by the applicant?

Yes we agree that there is no relevant technical alternative to the lead inside brass alloy.

c. Please explain why you either support the applicant's request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

There is a brass without lead content called ECO Brass (CW724R). However, this alloy has turned out to be unusable for us, as it does not have the technical properties we require, as described below.

The available substitute material is not machinable and does not have the electrical conductivity we require.

With the currently available alternative materials we have destroyed both cutting tools and CNC machine parts. Without the low lead content in the alloy, the material is not suitable for machining.

We have carried out many investigations both in the development of the brass parts and in the production process and must conclude that we, as a manufacturer of medical technology products, cannot use the available alternative material.

2. Please provide information concerning possible substitutes or elimination possibilities at present or in the future so that exemption could be restricted or revoked:

a. Please detail substitution and elimination possibilities and for which part of the applications in the scope of the requested exemption they are relevant.

If material producer develops new alloy in that way we are able to machine and our products are working with this alloy in terms of electric conductivity.

b. Please provide information on research to find lead-free alternatives (substitution or elimination) that may cover part or all of the applications in the scope of the exemption request at present or in the future.

The material should be machinable by CNC-lathe and milling machines and should correspond with lead-containing in electric conductivity.

c. Please provide a roadmap of such on-going substitution/elimination efforts and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

If we have alternative material, we could switch to it within 5 to 10 years. Because in the medical industry, we have to revise the risk assessment documentation for every part. And there are thousands of parts that need to be changed to a new material. Anyway, we don't have an alternative material, which means we have to take our

products off the market and lose most of our business if the exemptions are not extended. So not only do we lose a large part of our range, but Europe also loses one of the few manufacturers of diagnostic instruments with European production facilities.