Questionnaire 1 (Clarification) Exemption 29 of RoHS Annex IV

Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices (category 8)

Requested validity: 7 years

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR has submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that some information is missing. Against this background, the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 21 August 2020 latest.

2. Questions

1. You propose the following wording for the renewed exemption:

   Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices (category 8)

   This deviates from the current wording:

   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.

   a. Did you omit the industrial monitoring and control instruments, the cryo-cooler cold heads and the cryo-cooled equipotential bonding systems in the current wording because

      i. the exemption is no longer needed for these devices?

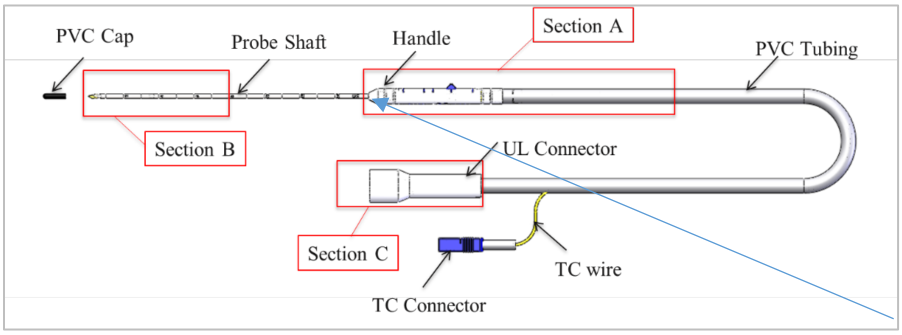
      COCIR has submitted this exemption request only to cover cryo-cooled cold probes in medical devices. We cannot confirm whether this exemption is needed for all of the other devices covered by exemption 29, although we are aware that it is no longer needed for cryo-cooler cold heads that are used in medical devices.

      ii. because you have no members producing industrial monitoring and control instruments which make use of this part of the exemption?

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

The applicants of this exemption request do not produce industrial monitoring or control instruments.

2. Your application contains two figures showing a cold probe and the related equipment. Could you please provide an outline illustrating where the lead-containing solder is used to bond the stainless steel, copper and brass elements to each other?



Lead solder is used here

3. You report trials made with lead-free solders, which, however, failed mainly due to poor wetting. Since wetting improves at higher temperatures, and the parts to be bonded are all metal parts which tolerate high temperatures.

    a. Which lead-free solders did you test?

    The solders tested were firstly a silver-bearing solder at 96% tin and 4% silver and secondly a lead-free solder at 97% tin and 3% copper.

    b. At which temperatures were the trialed alloys tested? Could the temperature be increased further to achieve proper wetting?

    The temperatures which the trialed alloys were tested was not captured by the reports generated at that time. Therefore, this information unfortunately cannot be shared.

    Solder wetting can be improved to some extent by increasing temperature, but only to a limited extent. Solder wetting is mainly affected by the effectiveness of the flux used to remove surface oxides. As bonding temperatures increase, so do the oxidation rates of solder metals and substrate metals. Solders require fluxes that function by removing surface oxides to allow liquid solder to interact with an oxide-free substrate. The ability of the flux to remove oxides depends on its composition and various solder fluxes formulations with differing reactivity are used. Fluxes for soldering to stainless steel need to be very aggressive as the oxide on stainless steel is very inert. When brass is heated, the zinc content rapidly oxidises to form zinc oxide and this needs to be dissolved in the flux. At higher temperature, much more oxide is formed and will overwhelm the fluxes ability to maintain an oxide-free surface.

4. You mention a feasibility study with a tin-copper-silver alloy (97% Sn, 0.25% Ag w/w, 2.75% Cu). When will these data be available?

The samples have been fabricated and are currently aging prior to testing, which is estimated to be finished October 2020. An indication on 'Testing of alternative materials in cryo-probes' as outlined in Table 1 of the exemption request therefore shall be completed in November 2020. It is important to note, although good progress is being made on the testing of this alternative the subsequent steps outlined in Table 1 are still required and are based on all tests being successful. Where possible the subsequent phases of testing shall be undertaken in parallel, however for the majority of phases they will need to be sequential due to the nature of any findings at each stage.

5. Cold probes are composed of brass, steel and copper parts.

    a. Why are three different metals/alloys used to form a cold probe?

    Brass tubing is used to carry high pressure Argon gas (at 3100 +100/-0 psi, 21.4 +0.7/-0 MPa) over a length of at least 96 inches (2.4 meters) from the control console to the cold probe while allowing flexibility such that the cold probe can be precisely placed during the treatment. Brass tubing provides for the critical parameters of high-pressure conveyance (strength) while more flexible than stainless steel.

    Most of the components of the cold probe are manufactured from stainless steel (alloys 303, 304, and 316L are used). These alloys are able to be readily machined or drawn into tubing having good diametrical dimensional tolerance along with excellent corrosion resistance (protective from the flux used to solder the components together). The strength of the stainless steel is also critical for its ability to withstand high pressure and significant temperature induced stress during use. The outer shaft component utilizes stainless steel as its surface and is required to be biocompatible and sterile during patient treatment.

    The copper component used in the cold probe is a very small machined finned-tube heat exchanger. Copper is used for its machineability and excellent heat transfer characteristics. Care is taken to thoroughly clean (to remove flux residue) the copper and brass components after soldering to avoid any future corrosion problems.

    b. Why are steel, brass and copper parts used? Could cold probes be produced from less metal parts with metals that are easier to solder?

    Beyond the reasons stated in part (a) of this question, stainless steel, brass and copper parts are used because they are all very satisfactory for use in creating strong soldered assemblies. Given the use of flux and proper soldering procedure, these materials allow for the solder joints to be formed with a very uniform and strong bond around the entire circumference of the tube-to-tube connections that are required.

    Any material changes would require testing to ensure that the performance of the alternative parts meet the same demanding criteria as the current design meets, which includes mechanical stresses due to the probes manual manipulation, high pressure gas and cold temperatures. It should also be noted that the Cryocare Surgical System and cryo-cooled cold probes are classified as Class IIa according to Annex IX, Rule 9 of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

6. Erbium-containing alloys were reported as potential substitutes in the last review of this exemption. Erbium is a critical raw material. Lead, however, meanwhile is a (REACh) substance of very high concern, and it may be adopted to REACh Annex XIV.

    a. Is there any research with these alloys, or are there plans for such research given the situation described above?

    It should be pointed out that erbium alloys were considered as substitutes for lead in cold heads of cryopumps. These alloys are not solders so cannot be used as substitutes for lead-solders used in cryocooled cold probes.

    b. What are the results of this research?

    Not applicable, see above.

Please note that answers to these questions will be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.