Questionnaire 2 Exemption 17 of RoHS Annex IV

Lead in solders of portable emergency defibrillators (category 8)

Requested validity: Until the end of 2025

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 5th July 2021 latest.

2. Questions

1. You indicated that additional approvals might be underway that COCIR cannot confirm due to the limited timeframe. Do you have new information about ongoing approvals since the first questionnaire?

   No further information can be shared at this time, other than the project to update affected AED products to comply with RoHS without the need for RoHS Annex IV, Exemption 17 is on-going.

2. You estimate that the transition to lead-free solders will be completed and approvals granted by the end of 2025. You also explain that only 10 % of the current models on the market are lead-free. The approval of the new designs is described as very time-consuming and costly. Nevertheless, the goal of a complete conversion of the remaining 90 % shall be reached in 4 years, while it took around 10 years to convert 10 % of models to lead-free. Based on your responses, this timeline seems very ambitious. How should the ongoing processes be accelerated to make the remaining 90 % of product lines lead-free in 4 years?

   Research and re-design work originally started before 2014 when Medical Devices entered scope of RoHS, so the 4 years to transition to lead-free only refers to the remaining work to be undertaken, rather the whole transition time. Wherever possible testing is undertaken to reflect the largest number of affected products so that the testing requirements are able to be utilized for more than one system. Of course, there are limitation to this strategy, for example when a circuit has to be redesigned, as well as gaining global approvals. It is not possible to this accelerate this process due to a limit on the number of expert engineers that are available, the elapsed time required for testing and the time needed to gain approvals.

3. You answered to the first questionnaire whether all models are used in all environments:
   "There are limitations to the types of use environments for some defibrillators. Some models have been

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

designed (including the use of lead-solder for shock and vibration) to be used in emergency responder vehicles intended for harsher use scenarios including the back of a vehicle and falling off a stretcher used in emergency settings. Whereas hospital versions of defibrillators are intended to sit on a stable cart, so experience some vibration and jolts, but are less likely to be dropped. Other environments that defibrillator models have been design for include the use in battlefield, commercial aircraft, marine environments and helicopters."

a. Are there specific product lines for specific fields of application as to the reliability in different environments? Viceversa, do all defibrillator models comply with all durability and reliability requirements of all the different environments in which defibrillators may be used?

All defibrillator models are required to comply with high durability and reliability requires due to the environment all of them are used in (drops, vibration, operating temperature, water resistance, dust resistance, cleaning etc.) and the high voltage requirement. There is subset of defibrillators which are specifically designed for the most demanding of environments, such as emergency responder vehicles. The durability and reliability of defibrillator is always reflective of the environment the equipment is design to be operated within.

b. Does the proportion of lead-free models available on the market change depend on the fields of application?

COCIR has not undertaken a full review of the lead-free models available on the market, but it seems reasonable to state there will be some correction between the field of application and the number of lead-free products. However, it is important to note that although this will be a contributing factor, other criteria which are not linked to the field of application may also play a part, such as a high durability requirement.

c. Conversion towards lead-free for most products in the past from around 2003 on were started with the least challenging ones. Can the 10 % of lead-free models be linked to less demanding applications, and if so, which ones?

No. Conversion to lead free models is based on both when the products were designed and the application in question. There is an example of an AED designed for public access and stored within a storage cabinet that has transitions to lead-free, however each model has to be considered under its own requirements.

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.