Questionnaire 2 COCIR Exemption 15 of RoHS Annex IV

Lead in solders for bonding to ultrasonic transducers

Acronyms and Definitions

IMCI	industrial monitoring and control instruments
Transducer	Ultrasound probe

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.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 24 September 2021.

2. Questions

1) COCIR:
You state that the conversion to lead-free of one type of transducer keeps a skilled engineer busy for at least one year. We wonder how to interpret this statement since we understand from other information you provided that a conversion of transducers to lead-free is only a small part of the efforts to achieve RoHS compliance. What you do is that you design new US transducers including the devices in/with which it operates to obtain a state of the art (new) model of medical device. Redesigning US transducers from lead-containing to lead-free US transducers does not happen unless you build a new model using parts of an older one in the course of the technical upgrades. In this sense, your statement that the conversion of one US transducer to lead-free takes one year per type of US transducers appears to be hypothetical for most of the cases.

   a) Is this our understanding correct?

   Companies use Full Time Equivalent (FTE) to assess the resources and time required by projects in project management. For instance it was used in the 2015 COCIR study to assess the cost of RoHS on companies :

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

RoHS COST CENTERS	COST (Mil €)
Supply chain management	19.6
Regulatory	4.3
Workload Full Time Equivalent (FTE)	164.2
Non Recurring Engineering (NRE), materials, testing	99.92
Additional/unexpected	3.4
IT infrastructure	4.3
Scrapping of parts	48.5
Request for Exemptions	36.4
TOTAL	**381.2**

When we say one engineer requires one year for the conversion to lead-free, we mean that, in the allocation of time and resources to R&D project for the release of a new lead-device 1 FTE is assigned to the lead-free conversion of the transducer.

As noted in the question, transducers are already lead-free. It is the bonding of the SC piezo element that contains lead. To accomodate the lead-free bonding, the architecture of the transducer has to be completely redesigned. Testing of both the solder and solder parameters is then required to ensure proper bonding, without damaging the sensitive piezo elements and long-term reliability of the new probe. It is worth noting that leaded solder bonds guarantee a nearly 100% reliability in the manufacturing process. This is not the case at lead free solders. Here extensive testing is necessary to avoid manufacturing caused product failures.

Transducers are expected to have a service life of over 6 years, in harsh conditions, so testing for mechanical robustness for example to IEC TR60721-4-7, Class 7M3, shock, drop, vibration test, cross sectioning and reliability testing all needs to be undertaken (all the joints, up to 28 for arrays, must endure a 10 times 1,50 m height drop on concrete floor test). Test procedure according to IEC / EN 60068-2-27. As explained, this work is estimated to correspond to 1 FTE.

In some cases it has not been possible to adapt the design to new bonding techniques and the result is that the trabsducer has been/will be discontinued.

b) If yes, how long does it take to redesign/develop a model as described above?

The design cycle of ultrasound equipment (time to bring a new concept/next generation to the market) is normally between 3 and 5 years, depending on the complexity of the devices being redesigned.

c) How long is the model life time of US devices normally before they are replaced by totally or partially new US device with improved clinical performance parameters?

The average lifetime of a single US device is between 5-6 years. For a transducer model to be withdrawn from the market, this can be up to 25-30 years, as the transducers are not linked to a US model, but rather the hardware technology is used intergenerationally. The improved clinical performance has been primarily driven by software and surrounding electronics changes, rather than hardware changes in the transducers, resulting in a very stable technology which has been utilised in a range of models.

For interest we have provided an image below of an example piezo element and its bonding.

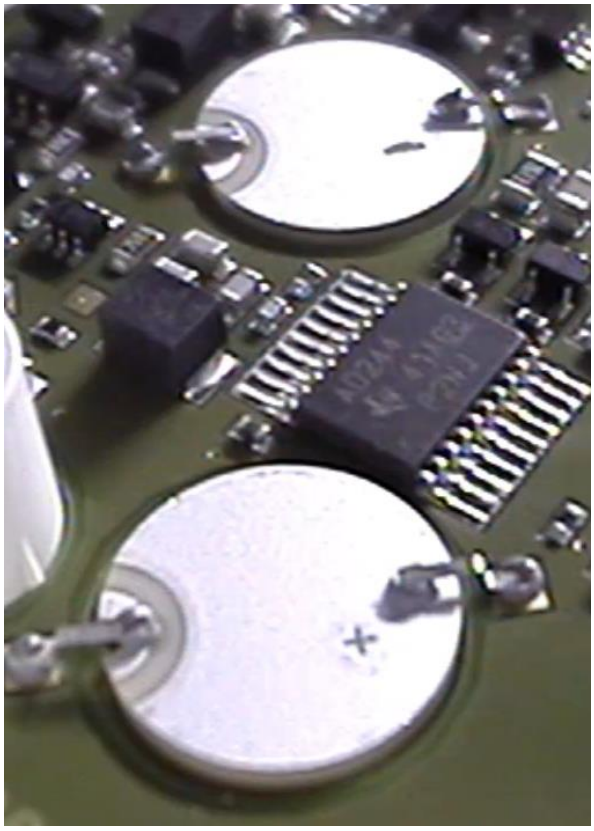

Figure 1

2) JBCE:
We assume that the approach is the same for cat. 9 devices other than IMCI in principle like described above.

a) Is this correct? Otherwise please specify the differences.

b) Please answer the above question b) and c) for cat. 9 EEE other than IMCI.

Please note that answers to these questions may be published as part of the review 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.

It would be help the review process if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.