

Questionnaire 4 COCIR Exemption 15 of RoHS Annex IV

Lead in solders for bonding to ultrasonic transducers

Acronyms and Definitions

IMCI industrial monitoring and control instruments

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed¹ 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 1 October 2021 latest.

2. Questions

- 1) You state in your exemption renewal request that one manufacturer could have 10 – 15 types of US transducers that use lead solders.

Could you please let us know at least one, better two or three manufacturers and their 10 to 15 types of US transducers?

Listing the specific manufactures which US transducers has not yet achieved RoHS compliance without the exemption is confidential as it can be a sensitive competitive information (please note that for certain exemptions COCIR Members have no information about which other competitor needs the exemption). However many companies list the large number of US transducers they currently sell on their respective websites, a proportion of which will utilise the exemption:

- <https://www.philips.co.uk/healthcare/solutions/ultrasound/ultrasound-transducer>
- <https://www.siemens-healthineers.com/en-uk/ultrasound/ultrasound-transducer-catalog>
- <https://www.gehealthcare.co.uk/products/ultrasound/ultrasound-transducers>
- <https://hcap.fujifilm.com/solutions/transducers/>
- <https://samsunghealthcare.com/en/products/UltrasoundSystem>
- <https://us.medical.canon/products/ultrasound/>

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

2) In case the exemption can be recommended for renewal, we would propose the below wording (cat. 9 not yet taken into account):

15	<i>Lead in solders for bonding to ultrasonic transducers</i>	Expiry on - 21 July 202x for cat. 8 medical devices other than in-vitro diagnostic medical devices for which the Declaration of Conformity is issued for the first time before 1 January 2014
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Would you agree to this wording?

Yes

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 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.