Questionnaire 4 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 10th of September 2021 latest.

2. Questions

In the last questionnaire, we discussed a possible subdivision of the exemption with you. Accordingly, the wording with your proposed changes would be:

17a	Lead in solders of portable emergency defibrillators	
(I)	Designed for indoor use (e.g. in hospitals, medical practices, companies, public buildings such as schools and authorities, private homes, etc.)	Expires on 21 July 2023
(II)	Designed for outdoor operations such as ambulances, helicopters, military purpose and big events etc.	Expires on 31 December 2025

After consultation with the EU Commission, we are continuing to pursue this option as well as the alternative of a certification approach in parallel.

As a general comment, it is COCIR's preference that the revised exemption scope is based on the first issue of the declaration of conformity, as suggested below. The rationale for this preference is based on the ability for the terms 'indoor use' and 'outdoor operations' to be clearly and consistently interpreted. These terms are not currently defined within legislation or standards, and as such although they can be logically understood the concern is that there may be variations in interpretation. This can cause legal uncertainty both to companies but to control authorities as well.

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

1. In the last questionnaire, we asked whether a clear subdivision of defibrillators is possible in terms of their area of use. You answered that: *"Equipment is qualified to different standards, with the selection of relevant standards driven by the expected operational environment of the equipment, for example RTCA DO-160G (Environmental Conditions and Test Procedures for Airborne Equipment) is known to be used for airborne equipment. However, the standards to which equipment is qualified to is not necessarily disclosed by the manufacturer."*

    a. Is the qualification to a specific standard related to the approval process by a notified body? Do defibrillators require additional standard conformity in order to use them in specific environments, for example harsh conditions?

    Standards are voluntary to demonstrate compliance to the EU Medical Device Regulation (MDR) in the EU Market because they are universally recognized and accepted. Other methods to demonstrate compliance may be used but Standards (EN, IEC, etc.) are universally accepted. The manufacturer must decide which standards are applicable to their device and the notified body provides approvals based on the compliance to the Standards identified and request evidence of testing and certification (e.g.: CSA Certification letter).

    As AEDs are medical electrical equipment, as such the 60601-1-1, or General Standard is automatically applicable to devices, as well as the particular standard for AEDs (IEC 60601-2-4) that our products must comply with. In addition to the baseline standards, there are collateral standards that we must comply with based on the device intended use. For example, there are Standards for hospital settings, home healthcare settings, emergency medical services, road vehicles, use in aircraft. Example: 60601-1-2 is applicable some devices which may be used in an environment where the presence of electromagnetic disturbances is present.

    The following is an example the of standards an example device complies with:

    IEC 60601-1:2005+A1:2012 – Medical Electrical Equipment – Part l: General requirements for Basic Safety and Essential Performance

    IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and tests

    IEC 60601-2-4:2010 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators

    IEC 60601-1-12:2014 - Medical electrical equipment- Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

    RTCA DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment

    b. The qualification to a specific standard is an important information and possibly also a sales argument. Is the conformity to certain standards obligatory for each defibrillator?

Yes, as referenced above compliance to the General Standard (606061-1-1) is required for all medical electrical equipment. Additionally, the Particular Standard for AEDs (60601-2-4) is also required.

c. If so, how is it possible that manufacturers do not disclose this information? How is such a standard useful otherwise? In case it is obligatory for use in a certain environment (previous question), it would even be obligatory to be disclosed.

Ultimately, the Standards or other method must demonstrate compliance to the EU MDR, as such the information is included in the DoC and checked by the Notified Body to ensure compliance with the standards referenced.

Also note, the intended use and indications of use for the device are described in the device instructions for use (IFU). The Notified Body ensures that these claims are valid by reviewing the standards for which evidence of compliance exists.

d. In case the standard conformity is not related to the approval process: Is the notified body approval then specific for the use environment?

We cannot make claims on intended use environment without evidence of safety and performance. To provide this evidence we test to all relevant standards, all of which is subject to Notified Body review.

e. You mention the standard for airborne equipment. In your exemption renewal request, you mention other harsh or at least challenging environments, e.g. use in ambulances. Are there standards available as well to which the defibrillators must be conform?

Yes, there are several standards available, the following are some such examples:

IEC 60601-2-4:2010 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators

IEC 60601-1-12:2014 - Medical electrical equipment- Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

RTCA DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment

None of these standards really allows for a clear distinction between “indoor” and “outdoor” use, as they are based on safety concerns and risk mitigation measures. The one for airborne equipment is the exception. Use in ambulances is not considered as it does not pose any additional safety risk compared to the use in “emergency service environment”. In general, unless the RTCA standard is used, it may be quite hard to demonstrate to which category a defibrillator belongs to.

f. The proposed wording (from the last questionnaire 3, see above) may remove individual models from the market. Are there specific models that would not be substitutable with technically/medically comparable models from the same or other manufacturers?

COCIR is unable to comment on if models will be removed from the market as we do not have knowledge of all AED manufacturers. However, it should be noted that in cases where a manufacturer must perform a design change to comply with RoHS requirements, there is risk the change could fall outside of the scope of EU MDR Article 120, Transitional Provisions.

Per Article 120, devices lawfully placed on the market pursuant to 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate, may continue to be made available on the market or put into service until 27 May 2025. This allows for a "Grace Period," in which manufacturers can continue to place devices on the market under their MDD certificates. **However, devices utilizing the "Grace Period," cannot undergo a significant change.** If the design change required to comply with RoHS requires a significant change, the manufacturer would no longer be able to place their device on the market without MDR approval.

Please note, MDR approval is a long process that is not necessarily due to companies' willingness to comply. A well know issue, is that there continues to be a shortage of Notified Bodies approved to perform conformity assessments to the EU MDR.

Note: RoHS Art. 5(1)(a) does not allow granting exemptions with the justification that not yet all manufacturers have converted all their models to lead-free versions. The only legitimate argument in this context would be if devices with specific properties could not yet be converted because of scientific and technical impracticability of substitution, possibly combined with adverse socioeconomic situations/impacts.

g. If so, why would manufacturers of such specific models not have participated in the exemption process either as applicants or supporting your exemption request, assuming that they are not members of COCIR?

When manufacturers see that an exemption is requested to be renewed, sometimes there is the assumption that the same scope of the exemption will be granted. As such, companies can be unaware of suggestions to change the scope of the exemption and therefore do not engage with the clarification question stage.
From experience with the past years, it is common to see companies, that are based extra-EU but sell in the EU, understanding that if an exemption is requested for renewal, then the renewal is granted. However, the mechanism of RoHS is not very clear to most companies and EC public consultations normally reach the same companies that are active already. This is even more true for companies manufacturing the components that are used in applications included in finished products (e.g. O_2 sensors).
This is probably the consequence of the RoHS Directive allowing a single company to submit a request without any need to involve other companies, as for instance required by the REACH registration process. The following is a list found online of defibrillator manufacturers, which while some of them may only manufacture active implantable devices and therefore be out of scope of the RoHS Directive, they could also have some pertinent input into the proposed scope:

- Asahi Kasei Corporation
- Philips Healthcare
- Defibtech, LLC.
- Cardiac Science
- Stryker
- CU Medical System Inc.
- Medtronic
- Boston Scientific Corporation
- Biotronik
- LivaNova Plc
- Abbott
- Microport
- Other prominent players

2. In the exemption renewal form you state that: *"Manufacturers have developed a few new defibrillators using lead-free solders since 2014."* Following this approach, the exemption could be split as follows to reflect conversion already done and to reflect this progress in the exemption scope:

17a	Lead in solders in portable emergency defibrillators.	
(I)	Defibrillators, for which the Declaration of Conformity of this model is issued for the first time before 1 January 2015	Expires on 31 December 2025
(II)	Defibrillators, for which the Declaration of Conformity is issued for the first time after 31 December 2014.	Expires on 31 December 2025

   a. Please kindly comment our proposal.

   The above proposal, with the originally proposed dates, is our preferred terminology to be used in the updated exemption scope. As before, an expiry date of 2024 is requested for 17a-I as there is an excessive risk that the timeframes for qualification could easily extended beyond the suggested timeframe of 2023. The availability of PCBA, as mentioned in our prior response, is continually adding to the overall qualification time. If the qualification is not completed by the expiry date there will be a gap in market availability of products, which has a detrimental impact on EU citizens health.

Please note that answers to these questions may 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.