

Consultation Questionnaire Exemption Annex IV n. 42

Exemption for “Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation”

Abbreviations and Definitions

RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
EEE	Electrical and Electronic Equipment
ACIST	ACIST Medical Systems
Hg	Mercury

Background

The Oeko-Institut has been appointed by the European Commission, within a framework contract¹, for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS), to be listed in Annexes III and IV of the Directive.

ACIST Medical Systems submitted a request for the renewal of the above-mentioned exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below. Additional information supporting this request can be found on the request webpage of the stakeholder consultation (<https://rohs.exemptions.oeko.info/exemption-consultations/2025-consultation-1>).

For further details, please check the exemption request and additional information submitted by the applicant on the request webpage of the stakeholder consultation.

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS 2), which can be found under:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>

¹ The contract is implemented through Framework Contract No. ENV.B.3/FRA/2019/0017, led by Ramboll Deutschland GmbH.

If you would like to contribute to the stakeholder consultation, please review the summary of the argumentation provided and answer the questions that follow.

1 Summary of argumentation of applicant on the justification of the exemption

This exemption relates to intravascular ultrasound imaging systems (IVUS), which is an imaging procedure that provides in vivo visualisation of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of the coronary artery wall. Mercury-based slip rings provide the electrical conduction path between the rotating transducer and stationary electronic equipment.

ACIST asks for renewal of the exemption. The applicant justifies its request for a renewal as follows: During the introduction and testing of mercury-free alternatives, no alternatives were found that meet the requirements for maintaining system performance for use in the ACIST HDi IVUS system. These requirements include, in particular, the frequency range of the signals to be transmitted (greater than 80 MHz), contact resistance (less than 1 Ohm), and more than 300 million rotations during lifetime). These requirements are essential for the usability, safety, function and reliability of the system. There is currently no validated substitute for the mercury-wetted slip ring.

2 Questions

- Do you agree with the arguments put forward by the applicants? Are there any additional reasons that support the requested extension of the exemption?
- Are the signal transmission requirements defined by the applicant technologically indispensable?
- In your opinion, what reasons oppose the requested extension of the exemption? In your opinion, are there other practical technological solutions, for example for contactless signal transmission?
- Are there any other aspects that you believe should be taken into account when assessing this application? Please provide relevant documents and evidence.

Responses submitted electronically will be posted on the RoHS Exemption Website site as they are received unless respondents specifically request that their contribution should not be published. In the latter case, responses should be clearly and visibly marked with the words "Not for publication".