MedTech Europe
from diagnosis to cure

Project Team RoHS Exemptions
Via BioIS
rohs@biois.eu

Brussels, 11-Dec-23

MedTech Europe recommendation for the extension of RoHS lead exemptions for medical technologies in the scope of category 8

Dear RoHS Exemptions Project Team,

On behalf of MedTech Europe, the European trade association representing the medical technology sector, I am writing to you to express our support for the renewal of the RoHS Annex III lead exemptions[1] launched for consultation under Pack 27 by the consultant BIOIS[2] and specifically category 8 medical equipment (*in vitro* diagnostic medical devices and other than *in vitro* diagnostic medical devices).

MedTech Europe recognizes the overall RoHS objectives and has collaborated with regulators and stakeholders on the exemption processes. We acknowledge that the evaluation of exemptions for a wide range of sectors and uses is a complex and lengthy task for the Commission, its consultants, and industry. We note that the present consultation focuses on the additional information supplied by applicants Test and Measurement Coalition and EUROMOT (categories 9 and 11 respectively), but that the "*The COM wishes the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories **8**, 9 and 11*"[3].

To this end, MedTech Europe would like to reiterate its support for the exemption renewal requests submitted by the 'Umbrella Project' in 2020[4] for the abovementioned exemptions, including for the category 8 medical technology uses.

- ✓ The medical technology sector is a downstream user of electronics and often **relies on components** provided by external suppliers who are the value chain partner responsible for RoHS compliance and for making their products available to many industries.
- ✓ The components subject to Annex III lead exemptions are used in a **wide range of medical technologies** in the scope of category 8 from surgical equipment, patient monitoring, and cardiac applications, to equipment used for the analysis of tissue, blood, and other human samples, to name a few.
- ✓ As argued in the 2020 exemption renewal applications, these exemptions are still required as there are **no suitable (technically nor economically feasible) alternatives**.
- ✓ Manufacturers of medical technologies use the same components as all other sectors of the electronics industry but can be seriously affected by early obsolescence of components (if drop-in replacements are not available), as **re-design** of medical technologies involves retesting, sometimes clinical trials, and gain

[1] Exemptions: 6(a) series, 6(b) series, 7(a), 7(c)-I, 15/15(a), 8(b), 13(a) & (b), 34
[2] Available at the link here: RoHS exemption evaluation - Homepage (biois.eu)
[3] Quote found in the 'batch 1 and 2' questionnaires launched for public consultation by BIOIS on 16 October 2023 and 9 November 2023
[4] Annex III lead exemptions submitted for renewal in 2020 as found in Packs 22-24, available on the website of Oeko Institute (Pack 22 & 24) and BIOIS (Pack 23)

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approval from Notified Bodies before re-designed products can be sold, per our stringent sectoral legislation[5].

- ✓ Considering there are no feasible alternatives, a non-renewal of Annex III lead exemptions for category 8 *in vitro* and other than *in vitro* could lead to the market discontinuation of some medical technologies, resulting in a negative impact on patient care.

The medical technology sector therefore needs a **maximum validity period** for category 8 of the Annex III lead RoHS exemptions. The needs of the sector were recognized in 2011 when categories 8 and 9 were included with longer transition timelines and validity periods for exemptions. Furthermore, the initial RoHS requirements did not apply to the medical sector until 10 years after the commercial industry, which allowed not only the manufacturers to transition all their components to RoHS 10 years before the medical sector needed them, but also gave 10 years of RoHS-compliant components to mature by the time the medical industry had to be fully compliant. Our experience shows that such long timelines are needed to match the design cycle and market availability of our products, as well as to bring products into compliance with RoHS and other legislation, including our sectoral legislation.

MedTech Europe is prepared to provide additional information on the category 8 uses of Annex III lead exemptions, should this be deemed necessary for the evaluation of these exemptions.

Best regards,

Sigrid Linher
Director, Sustainability and Environment
MedTech Europe

[5] Regulations 2017/745 (MDR) and 2017/746 (IVDR)