Consultation Questionnaire Response

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1. Do you agree with the arguments put forward by the applicant? Are there any additional reasons that support the requested revocation of the exemption?

Yes, I fully support the arguments presented by Butterfly Network. In addition to the justification provided, I emphasize that:
- Lead-free alternatives, including capacitive micromachined ultrasonic transducers (cMUTs), are technically mature, CE-certified, and already deployed across multiple EU healthcare settings.
- These alternatives reduce environmental and occupational exposure to lead—a known neurotoxin and align with the EU's broader circular economy and e-waste reduction goals.
- Manufacturers such as Butterfly have demonstrated large-scale production and clinical reliability using lead-free platforms, which indicates market readiness and practical feasibility.

2. In your opinion, what reasons oppose the requested revocation of the exemption?

From a technical and scientific standpoint, I do not identify any strong reasons to oppose the revocation for handheld devices. While other specialized clinical applications may still require exemptions temporarily, the use of lead in portable and handheld ultrasound transducers is no longer justified.

3. How do you rate cMUT technology in terms of image quality and reliability? What technical parameters are used to evaluate diagnostic procedures?

Based on peer-reviewed data and field observations:
- ***Image quality***: cMUTs provide resolution and penetration comparable to PZT-based transducers across a 1–12 MHz range.
- ***Reliability***: The technology has demonstrated robustness in clinical and field settings, including in high-heat and mobile environments.
- ***Key parameters*** include center frequency, bandwidth, sensitivity, signal-to-noise ratio (SNR), and axial/lateral resolution.
- Compared to conventional piezoelectric single-crystal materials (e.g., PZT), cMUTs match or exceed expectations for general diagnostic use in handheld formats.

4. How do you assess the potential negative effects of substitution on occupational health and consumer safety, reliability of the cMUT technology? How do you assess the overall benefits of cMUT technology for the environment, health and consumer safety?

There are no significant negative effects observed with cMUT substitution. On the contrary:
- Occupational and patient exposure to lead is completely eliminated.
- Device miniaturization and user-friendliness are enhanced.
- Environmental risks associated with lead disposal in e-waste are reduced.
- cMUTs also facilitate lower power consumption, improved heat dissipation, and easier sterilization.

Overall, the substitution has positive effects across all dimensions of health, safety, and sustainability.

5. Are there any other aspects that you believe should be taken into account when assessing this application? Please provide relevant documents and evidence.

Yes:
- The growing commercial use of Butterfly's handheld cMUT-based devices across LMICs demonstrates practical field applicability and reliability.
- See attached technical report and referenced peer-reviewed studies (Li et al., 2022; Yao et al., 2023; Zhang et al., 2024; Rao et al., 2024).
- Technological innovation in beamforming and signal processing has closed the historical performance gap.

6. What are the limitations of cMUT technology? Which applications cannot be replaced by cMUT technology but are possible with other handheld ultrasonic transducers or vice versa?

cMUT limitations include:
- Slightly lower acoustic pressure generation in certain high-impedance environments.
- Limited frequency performance beyond 15 MHz for deep penetration applications (e.g., some cardiovascular imaging).

However, these gaps are not relevant to most handheld applications, which prioritize portability, point-of-care utility, and diagnostic versatility.

7. How do you assess the EU's dependency on other countries in this sector? Would a revocation of the exemption increase the EU's dependency? If so, why?

Revoking this exemption is unlikely to increase EU dependency:
- Multiple manufacturers within and outside the EU are already transitioning to lead-free technologies.
- Encouraging adoption of cMUT and other non-lead alternatives will likely stimulate EU-

based R&D, reducing long-term dependency and positioning the EU as a leader in safe, green medical technologies.

Author Bio

Engr. Millicent Alooh, PhD(c), is an accomplished biomedical engineer and health technology leader with over 15 years of experience in medical equipment regulation, program implementation, and sustainable innovation across sub-Saharan Africa. She previously served as the Regional Director for Biomedical Engineering Implementation at NEST360, a multi-country initiative focused on improving neonatal health outcomes through appropriate medical technology. In this role, she led strategy development, policy engagement, and technical capacity building in Kenya, Malawi, Nigeria, and Tanzania, working closely with ministries of health, academic institutions, and regulatory authorities to embed robust health technology management systems at scale. Currently, she serves as the Head of Technical Services at HealthActive-Harleys Ltd, overseeing technical operations in Kenya, Tanzania, Uganda, and Mauritius. Engr. Alooh is a recipient of the AAMI Global Health Technology Leadership Award and the Kenyan Presidential HSC honor. She contributes her expertise to several national and international technical boards, including WHO's STAG MEDEV and the Kenya Bureau of Standards (KEBS).