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Annex IV / n. 14 Statement on the application of the company “Butterfly” for withdrawal of the exemption for lead-containing piezo material in ultrasonic probes.

1. Introduction and Summary

The Society for Ultrasound in Medicine – DEGUM e.V. was found in 1972 as an association of scientists and physicians. With more than 12,500 members, DEGUM is one of the largest medical-scientific societies in Germany and one of the largest ultrasound societies worldwide. It is dedicated to promoting science and research, public and vocational education, and public health and healthcare in the field of ultrasound. DEGUM organizes conferences, training and continuing education, is responsible for guidelines, sets quality standards, and monitors certification processes related to ultrasound procedures in medical diagnostics and interventions. Under the organization "EFSUMB," many DEGUM members operate throughout Europe and, sets global standards for the performance of ultrasound-assisted examination procedures and interventions.

In order to safeguard the achieved technical level of sonographic imaging and thus the current diagnostic confidence of sonography, **we strongly advocate not pursuing the application by the company "Butterfly" to revoke the exemption!** After reviewing the transducer system, advertised by the applicant and its technical implementation, we have to conclude that the manufacturer's product, offered as an alternative to conventional lead-containing piezoceramics, in no way comes close to the imaging accuracy achieved today in sonography. **We therefore consider it absolutely necessary at this time to maintain the exemption in the interests of comprehensive medical care based on accurate diagnostics!**

If, as a consequence of a revocation of the exemption and the resulting mandatory use of lead-free transducers, the quality level of ultrasound diagnostics regularly monitored by the health providers deteriorates, consequently cancellation of the health insurance-funded ultrasound diagnostics!

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2. technical Assessment

Sonography is established as a bedside, mobile, and cost-effective diagnostic and monitoring procedure in modern medicine. Technologies such as (Lead zirconate titanate) PZT and CMUT are used depending on specific applications. The ultrasound probes were specifically developed for this purpose and are optimized in terms of their aperture, acoustic power, bandwidth, disinfection regime, over its product life cycle. Long-standing experience with this high reliability of sonographic imaging in its wide range of applications is primarily available for PZT-based probes. The CMUT replacement technology presented by the applicant in Section 6B, which quotes "meets the highest quality standard for real-time scanning," is, however, incorrect in the following points. In order to ensure diagnostic reliability, other modes are equally important. In addition to the B-mode comparisons listed by the applicant, these not include Doppler, contrast-enhanced sonography, and shear-wave elastography. There are no statements regarding the equivalence of the diagnostic value of the CMUT probes for these imaging modalities, which are also not found in literature. The sample images submitted by the applicant do not demonstrate acceptable imaging quality. Important setting parameters are omitted, and a comparison of a curved abdominal probe with a linear CMUT is made, based on a fundamental difference in the acoustic properties. **Rather, the Butterfly CMUT system meets at best rudimentary requirements for the simplest diagnostic questions.**

3. Assessment of diagnostic confidence and reliability

Compared to conventional piezo-based ultrasound systems, the "butterfly device" presented by the applicant as an alternative, consistently demonstrates glaring weaknesses of the new technology. Experienced ultrasound examiners particularly criticize very limited spatial resolution, a poor signal-to-noise ratio, and insufficient differentiation between different tissue types. These performance deficiencies are clearly demonstrated, for example, in the attached publication (Appendix 1):

„Comparison of 6 handheld ultrasound devices by point of care ultrasound experts: a cross sectional study“ A Perez Sanchez, G Johnson, N Pucks et al. 2024 ;The Ultrasound Journal doi:10.1186/s13089-024-00392-3

Another comparison (see Appendix 2) demonstrates the qualitative deficiencies

of the Butterfly device compared to a more recent conventional piezo-based handheld system. The examining cardiologist particularly criticized reverberation and side lobe artifacts, as well as strong noise that overlays echo structures such as the heart valve leaflets and masks any thrombotic deposits in the apex of the heart. In particular, the short-axis (SAX) and four-chamber view (4Ch) were described as unacceptable and unusable. This is due, among other things, to the size of the capacitive transducer, which cannot be applied intercostal due to its lateral extension and causes acoustic interference due to the additional ribs being scanned (see Appendix 3). **Therefore, the CMUT system, advertised by the applicant as a lead-free alternative, is completely unsuitable for cardiological and pulmonary examinations!** This lack of suitability for important cardiological and other emergency medical issues is also described in the following study:

Appendix 4 :*“The Performance Characteristics of Handheld, Non-Piezoelectric Point-of-Care Ultrasound (POCUS) in the Emergency Department”* BM Wubben and HI Yun, Diagnostics 2023. doi: 10.3390/diagnostics14010017.

The study shows that, while the specificity was largely acceptable, the sensitivity for some organ structures, such as the heart or kidney, was completely inadequate. Some important pathologies, such as pneumothorax, were not detected using the butterfly system! The shortcomings of the applicant's capacitive transducer principle with regard to the fine resolution of small, delicate structures are clearly evident from the comparison in Appendix 5. The figure was adapted from the study:

Appendix 6: *“Performance of a Handheld Ultrasound Device to Assess Articular and Periarticular Pathologies in Patients with Inflammatory Arthritis”* G Sara Bayat, K Tascilar et al. 2021 Diagnostics doi:10.3390/diagnostics11071139

In this context, it is significant that legislators and the German Federal Joint Committee (GBA), relying on the high image quality of today's ultrasound systems, have introduced various preventive measures based on sonographic imaging (ultrasound as part of maternity guidelines, hip joint screening, aortic aneurysm screening, and advanced mammography screening). Sonographic fracture sonography has also recently been introduced for children to spare young patients suspected of having fractures from undergoing ionising X-rays examinations. Therefore, the GBA has established binding minimum technical requirements for these and other examinations in the so-called "Ultrasound Agreement" (Appendix 7), which must be met in outpatient care. Several of these minimum requirements are not met by the applicant's "Butterfly IQ" ultrasound system and therefore the CMUT technology!

For example, the following applications require an image width of at least 34 mm from the body surface to fully capture the structures being examined:

- Thyroid
- Facial soft tissue
- Paranasal sinuses
- Breast
- Musculoskeletal system

This minimum width is not achieved by the Butterfly system (<30mm); nor do the frame rate, image quality, and examinations documentation; meet the minimum requirements of the GBA ultrasound agreement. The system also does not have a simultaneous ECG lead, which is required for echocardiographic applications. **Therefore, the Butterfly system cannot replace conventionally designed ultrasound systems due to its lack of compliance with regulatory requirements!**

4. Safety Assessment

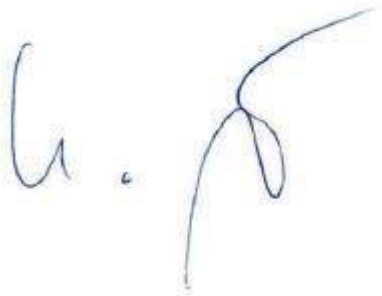
Currently, there are no studies demonstrating that PZT in ultrasound probes poses a contamination and thus a risk to patients and examiners. Lead contamination only occurs during the processing (sintering) due to outgassing at temperatures above 1000°C, which does not occur under disinfection conditions. The applicant does not demonstrate the robustness and reliability of its process compared to medical disinfection and sterilization regimes, which must not compromise sonographic quality over the product life cycle. The robustness and safety against mechanical forces and chemical substances is justified in Section 6B by reference to its use in Ukraine, which is insufficient because PZT-based transducers are also successfully in use there. Contrary to the applicant's statements in Section 8D (socio-economic impact), a replacement of PZT by the CMUT process requires a complete hardware redesign, particularly the frontend, of all medical systems currently based on PZT. The clinical trials required for new approval due to the high regulatory hurdles (MDR) would dramatically increase the costs of this diagnostic procedure, significantly limiting the benefits of sonography as a cost-effective bedside examination method. **This would harm patients and pose health risks to the general public due to underdiagnosis. The use of alternative X-ray-based diagnostic procedures would lead to an increase in radiation exposure in the population.**

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