Suggested email text to send to sante-med-dev@ec.europa.eu

To whom it may concern

It has come to our attention that there has been a Class III reclassification of “equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain”.

While Regulation (EU) 2022/2347 is related to “products without an intended medical purpose”, the description of the technologies as provided in section (7) of the reclassification, is so deeply flawed that it cannot stand unchallenged. Most importantly it does not reflect the available scientific evidence, it directly compares two fundamentally different technologies (limited output TES and TMS) and lists a number or risks that are not relevant for both, and it does not specify how the risks listed - and thus the reclassification - are only related to use without an intended medical purpose.

Until recently we were not aware of this formulation, and based on the very limited feedback to the public hearing it is our understanding that neither were other relevant parties in our field. Thus it is questionable whether the relevant parties have been sufficiently involved in the process.

Based on the above, it is our clear impression that the Committee on Medical Devices has failed to comply with the framework for Better Regulation, specifically the following two points:
1) an evidence-based approach — policy decisions need to be informed by the best available evidence (including scientific evidence, where available)
2) a participative approach — all interested parties, be they experts or individuals or groups affected by EU laws and regulation, should be able to contribute to policy making by expressing their views and providing relevant data;

Therefore, we request the implementation of Regulation (EU) 2022/2347 to be put on hold since it is not based on ‘best available evidence’, and a new hearing period to be put in place where we, and other relevant stakeholders, are able to provide our input to Section (7) in accordance with the Better Regulation principle of a participative approach.

I also want to emphasize that I fully endorse the statement and position as published by the European Society for Brain Stimulation (ESBS), which also contains many more relevant details.

All the best
[Your name]
[Your postal address - *mandatory*]
[Your institution/affiliation]
[Optionally: your number of years of clinical/scientific experience in the field of NIBS]