**Complaint form content:**

1. **On behalf of (if applicable):**

MY SELF, ANOTHER PERSON, ASSOCIATION/ORGANISATION/NGO, COMPANY, PUBLIC INSTITUTION, OTHER

Details of your complaint

2. **Against which European Union (EU) institution or body do you wish to complain?**

European Commission (EC)

3. **What is the decision or matter about which you complain? When did you become aware of it?**

The complaint specifically regards unit Medical Devices (SANTE.D.3), under Medical Products and Innovation; Deputy Director General for Health responsible for Directorates B, C and D; Directorate-General for Health and Food Safety.

SANTE.D.3 has produced and adopted on December 1st a new Regulation (EU) 2022/2347, and as part of Section (7) in the regulation they reclassify “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 as referred to in Section 6 of Annex XVI to Regulation (EU) 2017/745” to Class III. This complaint regards both the concrete content of Section (7) in (EU) 2022/2347, and the lack of stakeholder involvement in the process.

With the reclassification in (EU) 2022/2347, the Regulatory Committee on Medical Devices led by Medical Devices (SANTE.D.3) has failed in complying with the core principles of Better Regulation. It is a very serious breach of public trust if bureaucrats can freely produce and adopt deeply flawed regulatory documents, detached from the scientific community and without input from the parties directly impacted by the regulations.

We became aware of the draft implementing regulation Ares(2022)5696071 on October 30th, 2022, after the hearing period had ended, when it was shared with us by a scientist who stumbled across the document. Subsequently we learned that neither the scientific community nor the other companies in the industry were aware of the draft.

**Add annexes if necessary.**

● Annex 1 - xDatex\_My letter to SANTE

● Annex 2 - XDateX\_SANTE reply

● Annex 3 - XDateXA copy of the ESBS\_manifesto\_Jan16\_2023

4. **What do you consider that the EU institution or body has done wrong?**

With the reclassification in (EU) 2022/2347, SANTE.D.3 has failed in complying with the core principles of Better Regulation, specifically breaching 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 policymaking by expressing their views and providing relevant data;*

Furthermore, with the generalized risk formulations used about the technologies in Section (7), SANTE.D.3 risks to wrongly reclassify whole classes of technologies from Class IIa to Class III – regardless of intended purpose – as the reclassification does not argue for any difference in risk for medical versus non-medical use.

The result of these errors is that any use of these low-risk technologies will be overregulated based on unsupported, and scientifically incorrect wording in Section (7), which will limit EU patient’s access to effective and well proven treatments – and grossly complicate further EU research in the field.

1. Based on this vast amount of safety data collected over the past 30 years, several publications, meta-analyses, reviews, guidelines and consensus papers have provided peer-reviewed evidence-based assessments of the safety of two of the leading technologies in the area: transcranial magnetic stimulation, TMS (see e.g., Rossi et al., 2020) as well as low output transcranial electric stimulation, TES (see e.g., Antal et al., 2017; 2022; Bikson et al., 2018a; b; Caulfield et al., 2022; Zewdie et al., 2020). Based on these data, the current scientific and clinical evidence suggests both TMS and low intensity TES are safe treatment and research interventions with few and mild adverse effects.

Disregarding this overwhelming body of evidence, the adopted Section (7) classifies these technologies as Class III. In doing so, SANTE.D.3 and thus the EU has apparently assessed that these technologies pose a greater risk to patients' safety than does the state of the scientific research in the area. The reclassification is based on incorrect statements about TMS and low intensity tES, contradicts the available scientific evidence, and many of the stated claims and assumptions are false (e.g., it is claimed that TMS/tES can induce “atypical brain development” or “abnormal patterns of brain activity”). Finally, Section (7) directly compares radically different technologies without considering the significant differences in risk profile.

Hence Section (7) of (EU) 2022/2347 fails to be supported by best available evidence, confuses radically different techniques with equally different side effects (many of them are not side effects, but adverse effects), and exaggerates the actual risks associated with the technologies. Furthermore, while citing ‘available scientific evidence’, (EU) 2022/2347 fails to provide any evidence for the scientific foundation for these claims.

The European Society for Brain Stimulation (ESBS), an independent and professional association of medical doctors, psychologists, neuroscientists, and others practicing and interested in Non-Invasive Brain Stimulation (NIBS) techniquessuch as TMS and low intensity tES has, after they became aware of (EU) 2022/2347, published a formal opposition to the EU reclassification (annex 5). Here the above points, and other criticisms of the lack of scientific foundation for the description in Section (7), are detailed.

In addition to Section (7) of (EU) 2022/2347 not being based on the available scientific evidence, the process of involving stakeholders has also failed, as there has been no serious feedback received during the hearing process, looking at the few feedback entries (21) and the complete lack of input from the brain stimulation community.

Another critical point is that while the reclassification document in question does regard products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745, the specific formulation used does not relate to how the products are used. In the exact formulation in Section (7), the language does not regulate any type of use of the technologies, it regulates the technologies in themselves. The formulation in Section (7) is describing the technologies generally and lists (unsupported) risks related to the nature of the technologies regardless of use. Based on this, the reclassification is not effectively reclassifying non-medical use of the technologies, it is reclassifying the technologies in themselves.

This has serious implications for any use of the listedtechnologies and will risk impacting medical use and thus medical access for patients in the EU.

**5. What, in your view, should the institution or body do to put things right?**

Due to the severity of the neglect by the committee, to put things right we believe the following steps will be necessary:

1. Retract Section (7) from December 1st adoption of the reclassification while the dispute is being resolved

2. Issue a new hearing period for Section (7), and secure input from

a. The academic/scientific community

b. Relevant interest groups

c. Private companies impacted by the regulation

3. Rewrite Section (7), based on the available scientific evidence collected in step 2.

4. Publish an amendment to (EU) 2022/2347 with a revised Section (7).

6. Have you already contacted the EU institution or body concerned in order to obtain redress?

This is a **mandatory condition** for a complaint to be admissible. Evidence that you have contacted the relevant institution or body to seek redress must be annexed to the complaint form. Otherwise, you will be informed that we cannot deal with your complaint.

NO

Other

**If the complaint concerns work relationships with the EU institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff Regulations? If so, have the time limits for replies by the institutions already expired?**

YES (PLEASE SPECIFY)

NO

NOT APPLICABLE

**Has the object of your complaint already been settled by a court or is it pending before a court?**

YES (PLEASE SPECIFY)

NO

**SAVE**

Other information

**Do you agree that your complaint may be passed on to another institution or body (European or national), if the European Ombudsman decides that he or she is not entitled to deal with it?**

YES, I AGREE

NO, I DISAGREE

**Do you agree to participate in a short survey (about one minute in length), once your case has been closed, to help us improve the service we provide to complainants?**

The European Ombudsman wishes to give complainants the opportunity to express their views on how the institution deals with complaints, with a view to improving the service the Ombudsman provides. The survey is carried out through a survey tool on the Ombudsman's website. The replies received are processed in such a way as to ensure the anonymity of your response. If you do not wish to answer one or more of the questions, you will be free to move on to the next question. The [Head of the Ombudsman's Communication Unit](http://www.ombudsman.europa.eu/contacts) is responsible for this processing operation.

YES, I AGREE

NO, I DISAGREE

**SAVE**

**Information note on data processing and confidentiality**

Data processing

Complaints to the Ombudsman and related correspondence often contain personal data, such as names, contact details and other information relating to identifiable individuals.

There are rights and obligations under European law (Regulation 2018/1725) as to how personal data is handled by EU institutions, [**including the European Ombudsman**](https://www.ombudsman.europa.eu/en/how-we-process-personal-data-in-complaints/en). These include an individual’s right to obtain access to his or her own information held by this Office. To exercise these rights or to find out more, please contact our [**Office**](https://www.ombudsman.europa.eu/contacts) or our [**Data Protection Officer**](https://www.ombudsman.europa.eu/email?to=contactform_email_dpo).

If a person considers that the Ombudsman has not handled his or her personal data properly, he or she may contact the [**European Data Protection Supervisor**](https://edps.europa.eu/).

Confidentiality of your complaint and information

Complainants are requested to identify clearly any document or information that they consider to be confidential immediately on sending it to the Ombudsman.

Confidentiality can only apply if there would be some adverse effect if the information were to be disclosed. It might, for example, apply to financial information, commercially sensitive information or personal information about a private individual. Confidentiality cannot always be guaranteed. In particular, if you submit to the Ombudsman documents that contain the personal data of someone other than yourself, that person will most likely be able to obtain it from the Ombudsman, exercising their data protection rights. In any event, you should expect your complaint and any supporting documents to be shared in full with the institution or body you are complaining about, so that they can properly understand it and respond to the Ombudsman.

I have read the information

I want to receive a copy of my complaint by e-mail