European Ombudsman

The decision by the European Commission to revise the risk classification of devices involving brain stimulation under rules governing products without an intended medical purpose in the context of the EU Medical Devices Regulation

Case 157/2023/VB - **Opened on** 15/03/2023 - **Decision on** 25/04/2024 - **Institution concerned** European Commission |

The complainant, a manufacturer of devices involving brain stimulation used in certain treatments, was concerned by how the European Commission adopted an 'implementing regulation' to revise the risk classification of such devices in the context of the EU Medical Devices Regulation. In particular, he contended that the Commission had failed to seek sufficient scientific assessment or consult with stakeholders.

The Ombudsman opened an inquiry [Link] and sought to meet with the Commission.