Dissenting vote of the endorsement and publication of the document MDCG 2022 - 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices.

Rationale:
Contrary to the intentions of a MDCG Guidance this document does not achieve an improved and more consistent understanding of the demarcation between MD and MP.

In particular, the modified definition of "pharmacological means" is insufficient as it does not define the term precisely but creates room for interpretation and uncertainty, when compared with the old definition. The new expression "typically at a molecular level" does not limit an interaction to this level, but provides an opening for further modes of action including physical interaction. This counteracts the intention of the Guidance to define terms precisely.

According to the Guidance a product cannot be qualified as a medical device within the meaning of Article 2(1) of the MDR if it cannot be determined, that the product's principal intended action is achieved by other than pharmacological, immunological or metabolic means.

This compels the manufacturer to prove the absence of a pharmacological effect when justifying the qualification as a medical device, which is impossible by using the definition provided. The same applies for devices incorporating, as an integral part a substance and for the application of Annex VIII, Rule 14 MDR.

The vague definitions do not support effective and aligned implementation of the legislation. Uncertainties among manufacturers, notified bodies and authorities should be avoided. This Guidance does not provide a common understanding of how the MDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.