Diverging opinion in compliance with Art. 103.4 concerning the endorsement of MDCG 2022 - 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices.

Rationale:
The MDCG 2022-5 Guidance does not achieve its purpose to clarify the demarcation line between medical devices and medicinal product.

The mode of action to qualify a substance as a medical device or a medicinal product is not sufficiently clear.
In particular, the amended definition of "pharmacological means" is insufficient to clarify the issue. Although the introduction of the concept "typically at a molecular level" can help, on the other hand it's still not enough to a clear application.

Moreover the conclusions reported in the guidance in relation to devices incorporating, as an integral part a substance which, if used separately, would/may/can be considered a medicinal product, are controversial causing confusion in the application of the rule.

These uncertainties do not help in a proper implementation of the legislation and should be avoided. The guidance does not provide a proper tool to an harmonized implementation of the MDR.

Since this guidance will be a broad consultation tool used by all the actors, we consider it's of primary importance that it is clear. The current version contains some critical elements which cannot be considered clear enough to guide stakeholders and CAs.

Changes to the guideline are necessary, in order to have an adequate instrument in line with the provisions of the regulation, for this reason we are not able to support its endorsement.