MDR: Revision process and amendments

Purpose of this document: *to provide a brief overview of the ongoing MDR simplification process during the CED Board meeting of September 2026. Please note that in light of the large number of amendments, a more detailed document (with the text of the amendments) will be provided to the WG Dental Materials and Medical Devices. This document is currently being finalized as such please consider the analysis below as a preliminary (internal) version for information*.

Current process: The file is currently at first-reading committee stage in the European Parliament, with the SANT Committee responsible and Oliver Schenk (EPP) as rapporteur. The draft report was published on 30 June 2026 and the amendments were tabled over summer. As a reminder, CED provided a set of amendments to some of the main MEPs involved in the process (e.g. shadow rapporteurs). The next phase will involve political negotiations within the Committee, including negotiations between the rapporteur and shadow rapporteurs, with a view to developing compromise amendments and agreeing the Parliament's position. The SANT Committee will subsequently vote on the report and amendments. In parallel, the Council is considering the Commission proposal, and the eventual legislation will need to be agreed between the European Parliament and Council.

Next steps: For CED, the period ahead of the SANT vote represents an important window for advocacy: nevertheless, engagement should focus less on the large number of individual amendments (over 800 in total) and more on ensuring that the emerging compromise text reflects dentistry's key priorities—e.g. in relation to well-established dental technologies, appropriate requirements for dental implants, and reduction of unnecessary administrative burdens without weakening patient safety.

Overall direction of the current amendments:

The amendments under consideration point *overall* towards a simplification of the Medical Devices Regulation (MDR), with the intention of reducing unnecessary regulatory burden while maintaining patient safety, traceability and appropriate clinical oversight. For dentistry, the amendments are particularly relevant in relation to well-established technologies, implantable devices, reprocessing and reuse, information requirements, and the treatment of well-known or lower-risk devices.

- **Well-established technologies:** A central theme is the concept of "well-established technology" (WET) devices. This could be important for dentistry, since many dental devices and materials are well known and used safely for many years (as the CED has been actively advocating in the past years). For example, one amendment explicitly recognises dental devices alongside other devices as possible well-established technologies. Other amendments seek to make the WET concept more objective, harmonised and consistently applied across the EU. There are also overlapping 'narratives' over whether WET status should be determined through broad criteria or by means of an exhaustive EU lists.

- **Traceability:** Here, there are discrepancies in the amendments between simplification and preserving traceability. Some amendments would maintain full implant-card and information requirements for all implantable devices, while others propose more targeted exemptions.
- **Reprocessing/single use devices:** on this issue, several amendments would place responsibility on the manufacturer to determine whether a device is intended for single use or may be safely reprocessed, based on its design, materials and physical, chemical and biological properties. Other amendments state that reprocessing or full refurbishment should only take place where safety and performance can be maintained (and many instruments in dentistry are a subject of cleaning, disinfection, sterlisation for a number of times), and that the party carrying out full refurbishment should assume manufacturer-level responsibilities, including labelling, traceability, post-market surveillance and vigilance.
- **Information and language requirements**: the amendments recognise that professional users may not always require all information in every national language and suggest that Member States should consider accepting other EU languages commonly understood in the medical field professional use devices.