Feedback:

The Council of European Dentists (CED), representing over 340,000 dentists across Europe, welcomes the Commission's proposal to amend the Medical Devices Regulation. In particular, the CED supports the elimination of the five-year validity period for certificates, viewing it as a significant step toward reducing the administrative burden on manufacturers. For healthcare providers and particularly for the dental sector, this transition is vital to ensuring the continuity of the supply chain and safeguarding the availability of essential medical devices without the pressure of unnecessary cost increases.

While the abolition of fixed 5 year validity period for certificates is a major regulatory advancement, the current wording may still introduce some regulatory uncertainties. The broad discretion granted to Notified Bodies to impose "specific conditions or limitations" and to conduct "proportionate reviews" is not yet supported by sufficient methodological detail. In the absence of a harmonized assessment framework, this could lead to differences in interpretation and application among Notified Bodies, where comparable devices could potentially be assessed differently depending on internal policies or practices. This lack of clarity may replace a predictable administrative hurdle with a less predictable review process, creating ongoing uncertainty for manufacturers and other stakeholders. Such uncertainty could also have consequential effects on the healthcare sector, potentially impacting device availability, timely patient access, and planning for clinical use.

The imposition of specific conditions or limitations on a certificate's validity would benefit from clear justification and reference to harmonized guidance, ensuring that such requirements remain proportionate to the clinical risk and do not place unnecessary administrative burden on manufacturers. Furthermore, surveillance intervals should not be established at the sole discretion of Notified Bodies. Instead, they should be determined in coordination with relevant stakeholders to ensure that timeframes remain reasonable and proportionate. Excessively short review cycles risk placing a disproportionate burden on clinical operations without corresponding safety benefits. Similarly, establishing some shared guidance on appropriate intervals for periodic reviews based on risk class could be beneficial, helping to reduce the risk that Notified Bodies might apply shorter review cycles to lower-risk medical devices. Without some level of shared framework, this may lead to a fragmented market where "indefinite validity" is applied inconsistently, making it more challenging to anticipate long-term compliance costs or timelines.

Additionally, as indicated in the proposed Article 56, the notified body's authority to limit the period of validity in exceptional cases based on duly justified grounds should be restricted specifically to higher-risk devices. Extending this approach to lower-risk devices, would risk creating disproportionate administrative burden without clear added safety value. Moreover, as the term 'exceptional cases' remains undefined, there is a risk of subjective interpretation by Notified Bodies, which could undermine the uniform application of certificate validity periods. To support consistency across the Union, additional guidance or illustrative examples should be provided to clarify the situations in which limiting a certificate's validity would be appropriate. This approach could help maintain the intended principle of 'indefinite validity' while promoting a level playing field and reducing potential differences in practice. Consistent application is essential to safeguard the healthcare sector, as it directly ensures device availability, enables reliable planning for clinical use, and maintains timely patient access to essential medical technologies.

Furthermore, the proposed amendments introduce greater flexibility in the equivalence pathways (Article 61 MDR), refining the clinical evaluation framework and supporting a smoother transition from the initial MDR rules. By allowing manufacturers to leverage clinical data from established technologies, the proposal promotes market continuity and innovation while maintaining patient safety and supporting the healthcare sector's ability to access essential medical devices reliably.

Despite the merits of this increased flexibility, the absence of precise definitions for 'similar materials' and 'technical equivalence' remains a significant concern. Clarifying these criteria would enhance predictability for the industry and help ensure that healthcare providers can continue to rely on consistent, safe, and timely access to medical technologies.

Additionally, while the proposed amendment on single-use devices tackles on "disposable culture", the provision stating that a person who fully refurbishes a single-use device shall be considered the manufacturer may give rise to concerns. Even where a device is only sterilised as part of routine reprocessing, unclear labelling could create ambiguity as to whether refurbishing has occurred, potentially exposing dental professionals to unintended liabilities. Clear and explicit marking of reprocessable devices on packaging or accompanying documentation would therefore be essential to ensure a clear distinction between sterilisation and full refurbishment.

Lastly, the proposed definition of Well-Established Technology (WET) relies on qualitative terms such as 'simple,' 'common,' and 'stable design', which requires further clarification to avoid divergent interpretation. In a regulatory context, these descriptors could lead to varying interpretations among Notified Bodies and national authorities, potentially affecting the consistency of the framework. Without clear, objective thresholds, manufacturers may face less predictable assessment outcomes, which could limit the

intended administrative relief. The establishment of a comprehensive 'Positive List' or binding technical guidance with measurable criteria, such as years of market presence and clinical data volume, is essential to ensuring regulatory coherence and maintaining uninterrupted access to safe medical technologies across the Union.

In conclusion, the Council of European Dentists supports the transition toward indefinite certificate validity, provided it is underpinned by clear and harmonised criteria. Establishing precise definitions and objective thresholds for the aforementioned amendments is essential to avoid fragmented implementation and to ensure the continued availability of safe dental technologies across the Union.