

WG Dental Materials and Medical Devices

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CED General Meeting**

May 2026



Medical Devices Regulation Proposal

Medical devices and in vitro diagnostics – targeted revision of EU rules

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- The maximum period of **validity of certificates** (currently 5 years) is removed.
- Instead of recertifying devices, notified bodies will carry out periodic reviews proportionate to the risk of the device while the certificate is valid.



Strasbourg, 16.12.2025
COM(2025) 1023 final
2025/0404 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

{SWD(2025) 1050-1052 final}

(Text with EEA relevance)

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Well-Established Technologies (WET)

- relatively simple, common, and stable designs with little evolution
- a well-known safety profile with no significant safety issues in the past
- well-established clinical performance characteristics
- a long history on the market.

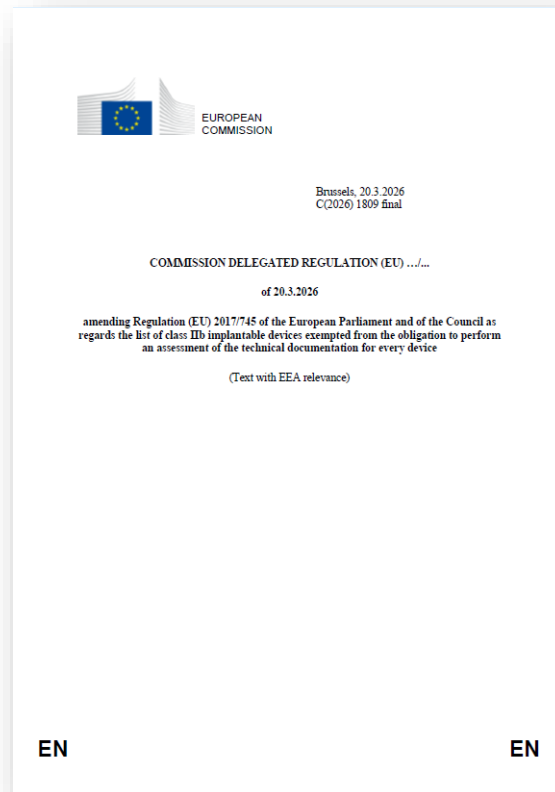


Well-established technologies (MDR: Article 2, point 72, Article 18, Article 32, Article 52, Article 61, Article 86)

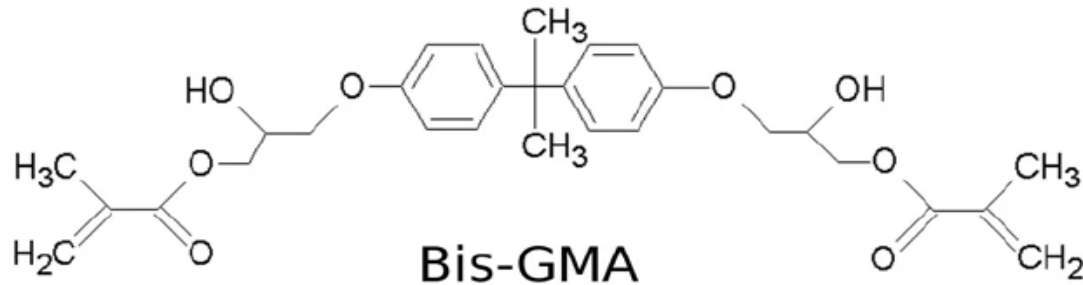
A definition of ‘well-established technology device’ is introduced for devices which will be subject to more proportionate requirements, replacing the lists of devices in the current Articles 18(3), 52(4) and 61(6)(b) MDR.

Well-Established Technologies (WET)

Title	Topic	Action
Commission adoption		
<u>Medical devices – expansion of the list of well-established technologies</u>	Public health	Published for information



Inquiry: Bis-GMA



No Environment Leakage: Application method prevents Bis-GMA release.

Stable Bonds: GMA release is impossible under normal oral conditions; requires extreme chemical environments.





**THANK YOU FOR
YOUR ATTENTION**

