

DTA MEMBER ALERT

European Commission Proposes to Delay MDR Transition



DENTAL TRADE ALLIANCE

On Friday, January 6 the European Commission adopted a proposal to allow medical device manufacturers additional time to comply with the EU Medical Device Regulation (MDR). To help ensure the availability of safe and essential medical devices, the Commission also proposes the repeal of the MDR “sell-off” date for medical devices sold into the European market.

Based on the proposal, the compliance dates will be extended to December 31, 2027, for higher risk medical devices. While medium and low risk medical devices are extended to December 31, 2028. The proposal also provides an extension of May 26, 2026 for class III implantable custom medical devices.

This proposal will next move to the European Parliament and Council for final approval. Please visit the links below for the latest information on this important compliance issue:

- [European Commission January 6, 2023 MDR Press Release](#)
- [European Commission January 6, 2023 MDR Questions & Answers](#)
- [European Commission Draft Proposal to amend the MDR regulation](#)
- [European Commission Moves to Delay MDR Transition, Regulatory News, January 6, 2023](#)

The Dental Trade Alliance (DTA) will continue to monitor and provide information to our members on this important compliance issue. Should you have any questions on this issue, please contact DTA Regulatory Counsel Rick Van Arnam at rvanarnam@barnesrichardson.com or DTA's Fred Freeman at fredfreeman@dentaltradealliance.org.