

December 14, 2022

The implementation of [Regulation \(EU\) 2017/745 on medical devices](#) (MDR) was discussed on the second day of the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) on 9 December 2022. The European Commission proposes to extend the transition period currently foreseen in the MDR for devices certified in accordance with the Medical Device Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD) through legislative amendment of the transitional provisions of the MDR. The extension of the transition period would be in the form of a staggered approach based on the risk classification of devices.

The transition period foreseen in the MDR provides that the deadline for recertification of medical devices in accordance with the regulation is 26 May 2024. A broad range of stakeholders, including the medtech industry, consider this timeline to be unattainable and have called on the European Commission to extend the recertification deadline. This extension would be based on the risk classification of devices and would mean that devices certified in accordance with the MDD and the AIMDD will remain on the market in the European Economic Area (EEA) after the end of the currently applicable transition period.

The European Commission proposes the following targeted legislative amendments:

- Extension of the transitional provisions foreseen in the MDR based on the risk class of each device.
 - 26 May 2027 for high-risk (Class III and Class IIb) medical devices
 - 26 May 2028 for medium- and low-risk (Class IIa and Class I) medical devices
- Elimination of the sell-off date of 26 May 2025 for medical devices that are already available on the EEA market to prevent safe medical devices from being removed from the market.

EU Commissioner for Health and Food Safety Stella Kyriakides noted that the proposed amendments would apply solely to medical devices that are safe for patients.

Following discussion with the health ministers of the EU member states, Kyriakides acknowledged the need for interim measures in relation to CE certificates of conformity previously issued for medical devices that have expired or will expire soon.

Shortly after the EPSCO meeting concluded, the European Commission published a [position paper](#) prepared by the Medical Device Coordination Group. The purpose of the position paper is to ensure a uniform approach to the application of market surveillance measures to bridge the gap between the expiration of certificates and the issuance of new certificates. The position paper provides guidance on how competent authorities should apply Article 97 MDR to devices that do not comply with the MDR due to expiration of their CE certificates of conformity issued in accordance with the MDD and the AIMDD before being certified under the MDR.

In addition to the proposed legislative amendments, the European Commission intends to undertake a comprehensive evaluation of the MDR by May 2027. The purpose of the evaluation is to identify structural problems with the MDR, as well as potential medium- and long-term solutions to these concerns. Moreover, the European Commission intends to fund actions to support the implementation of the MDR under the EU4Health programme starting in early 2023.

If you have any questions about the effect of the extension of the MDR transition period, please reach out to a member of your Cooley life sciences regulatory team.

This content is provided for general informational purposes only, and your access or use of the content does not create an attorney-client relationship between you or your organization and Cooley LLP, Cooley (UK) LLP, or any other affiliated practice or entity (collectively referred to as "Cooley"). By accessing this content, you agree that the information provided does not constitute legal or other professional advice. This content is not a substitute for obtaining legal advice from a qualified attorney licensed in your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our [legal notices](#).

Key Contacts

Jessica Koffel Brussels	jkoffel@cooley.com +32 2 486 75 25
----------------------------	---------------------------------------

This information is a general description of the law; it is not intended to provide specific legal advice nor is it intended to create an attorney-client relationship with Cooley LLP. Before taking any action on this information you should seek professional counsel.

Copyright © 2023 Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304; Cooley (UK) LLP, 22 Bishopsgate, London, UK EC2N 4BQ. Permission is granted to make and redistribute, without charge, copies of this entire document provided that such copies are complete and unaltered and identify Cooley LLP as the author. All other rights reserved.