

THE MDR JOURNEY

«Let's make transparency
a standard requirement»

NEWSLETTER N. 29 – December 2022

Subject: Proposal for extension of the MDR transitional period for legacy devices

On Dec. 9, 2022, at a meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) with the European Union health ministers in Brussels, there was a discussion regarding challenges in the implementation of the Regulation (EU) 745/2017 on medical devices (MDR), and risk of device shortage after the end of the transitional period. As a result, the European Commission has proposed to extend the transitional period for the “legacy products”, which are the products currently certified according to the Council Directive 93/42/EEC (MDD).

The current MDR transitional period for MDR certification of legacy products is May 26th, 2024 which is considered unattainable by a significant part of stakeholders, including the MedTech Industry.

The amendments proposed by the European Commission include the following:

- Extension of the transitional period according to device risk class:
 - May 26th, 2027 for higher medical device risk classes, class III and IIb
 - May 26th, 2028 for medium and low risk classes, class IIa and I
- Deletion of the sell-off date of May 26th, 2025 for MDD medical devices that are on the market

Next steps by the European Commission are expected within the first quarter of 2023. In any case, At STS we continue our efforts for a smooth transition to MDR according to the transitional periods established.





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This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 “Systems and Procedure Packs”.

We are already today all dependent on efficient cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.

We are confident we will continue to supply health care competently on customized surgical procedure sets and small kits.

Do you wish to know more about specific MDR topics? Do you have any questions or comments about STS newsletter? Write us at MDR2020@stsmedicalgroup.com.

The next MDR newsletter will be issued in January. We take the opportunity to wish everyone a merry Christmas time and a great start for the new year 2023.

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