

# inform<sup>®</sup>

## European Commission Proposes 1-Year Delay in MDR Application Date

On April 3<sup>rd</sup>, 2020, the European Commission proposed a 1-year delay of the Medical Device Regulation's compulsory application date<sup>1</sup>. If this proposal is implemented in its current form, the MDR will apply from May 26<sup>th</sup>, 2021, instead of the original application date of May 26<sup>th</sup>, 2020. This also means that Class I medical devices compliant with the Medical Device Directive 93/42/EEC can continue to be marketed without the need of economic operators to implement the additional rules contained in the MDR until May 25<sup>th</sup>, 2021.

Further we have noted that the end of the period for making available MDD devices remains unchanged (May 27<sup>th</sup>, 2025) as well as the UDI implementation deadlines for class I (May 26<sup>th</sup>, 2025) and class IIa and IIb (May 26<sup>th</sup>, 2023).

In a previous Informs, we shared with you that all **Sempercure**<sup>®</sup> examination gloves as well as **Semperguard**<sup>®</sup> protective gloves that are classified as medical devices already comply with the MDR. The proposed postponement of the MDR won't have any influence on our already compliant Class I medical devices.

The coronavirus pandemic has put a significant strain on the resources of medical device manufacturers, notified bodies and national authorities, and this proposal will allow them to better focus on work directly related to the ongoing health crisis. Rest assured that our work to ensure our products' compliance continues uninterrupted and remains on schedule.

We will keep you informed on further development as soon as we receive more information. Kindly contact us if you have any questions.

Your Sempermed Team



<sup>1</sup> Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:144:FIN>