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April 2023

RE: Extension of MDR transitional period.
To whom it may concern,

Dear Merit Customer,

As part of our commitment to inform you proactively, we want to share the following information with you.

The prolongation of the MDR, described in Regulation (EU) 2023/607, dated March 15, 2023 has been published in the Official Journal of the European Union and came into effect immediately.

In short, this amendment means the following:

Under conditions now defined in the Regulation, the (expired) MDD CE Certificates are automatically extended until May 26, 2024. The Notified Body will NOT issue a new Certificates with new expired dates. Merit is allowed to and will issue Self Declaration letters confirming that the conditions for the extension are fulfilled. Hence, until May 26, 2024, a supportive letter from the Notified Body is not required.

Further extension of the MDD CE Certificates is possible under several conditions for a period until December 31, 2027, or December 31, 2028 depending on the device's risk class. Merit fulfills these conditions and has lodged formal MDR applications with their notified body to be granted this further CE Certificate extension.

Merit is dedicated to delivering solutions to healthcare partners and providing the highest quality products and service for the care of your patients and appreciate your continued support and business.

Should you have any questions, please contact your Merit Sales Representative or Regulatory Specialist.

Very truly yours,

DocuSigned by:

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Stephan Hendriks
Senior Director, Regulatory Affairs