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CooperSurgical®

October 30 2023

Dear Customer/ Business partner:

Re: Coopersurgical EU MDR remediation status update

This letter provides an update to CooperSurgical's progress towards the MDR compliance, as well as the documentation status in support of the MDR extension (EU) 2023/607 amending regulations published in March 2023.

As a recap, on May 26, 2021, the European Commission mandated the MDR compliance for all products. For any class I (Self-declared) legacy medical devices products, companies need to have now fully complied with the MDR requirements. For any class of medical device which requires Notified Body involvement under MDR, companies need to maintain MDD compliance if they want to take advantage of these extension periods to continue selling these products to the EU market. The recent MDR amendment released in March 2023 revealed the following extensions:

- Extended from 26 May 2024 to 31 December 2027 for higher risk devices (Class III and IIb implantable)
- Extended until 31 December 2028 for medium and lower risk devices. (Class IIb (non-implantable) and IIa, Im, Ir, Is)
- Remove the 'sell-off' date currently established in MDR and IVDR

To ensure product availability in the EU market as well as CE Mark regulated countries, CooperSurgical Inc. is continuing with our product MDR certification effort and will continue to maintain MDD compliance of our devices, where necessary in accordance with the conditions of the extensions. CooperSurgical has secured the self-declaration letters based on our Notified Body BSI's guidance, allowing both compliance and continuous product availability until the MDD extended period expiration. CooperSurgical also instigated plans to deploy processes to ensure compliance with the new MDR requirements throughout the different stages of implementation, including subsequent registrations efforts globally to reflect the MDR related impacts.

CooperSurgical expects minimum changes to our product portfolio offering because of EU MDR. We continue to work with the Notified Body British Standards Institution (BSI) and have secured a successful MDR certification contract with BSI and are in active process of technical documentation submission as well as receiving technical and MDR certification audit approvals.

CooperSurgical will continue to communicate during this regulatory transition period, and we thank you for your continuous support and partnership.

On Behalf of Cooper Surgical, Inc.

Charles Smith

Charles Smith (Oct 31, 2023 11:19 PDT)

Chad Smith

EVP, Life Sciences Services & Innovation, Operations Management

Oct 31, 2023

Date







MDR Compliance Statement 2023-10-30 -Final

Final Audit Report

2023-10-31

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