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An Asahi Kasei Group Company

October 22, 2020

Dear Customer:

At ZOLL Medical Corporation, we are aware that European Regulation (EU) 2017/745, commonly referred to as the European Medical Device Regulation (MDR), implementation date has been extended from May 26, 2020 to May 26, 2021.

This letter is to ensure you that ZOLL is taking all necessary steps to guarantee the availability of products during and after the transitional phases of the MDR.

The European Medical Devices Regulation (MDR) entered into effect on May 25, 2017 and marked the start of a three-year transition period, originally ending on May 26, 2020, now May 26, 2021. During this first transition period, manufacturers are expected to update their quality management system to meet MDR requirements. A second transition phase will end on May 26, 2024, when existing CE marking under Medical Device Directive (MDD) will expire. Manufacturers will have a transition period to apply for certification under the MDR for devices currently certified under the Medical Devices Directive (MDD). Certificates issued to the MDD during the transition period will remain valid for the entire period, unless that exceeds four years after the date of application.

ZOLL Medical Corporation has received recertification of CE marked products under the MDD, valid until May 26, 2024. We expect that recertification under MDR of all our CE marked products will be completed before May 26, 2024.

If you have any additional questions, please see attached the FAQs document for additional support as we transition to the European Medical Devices Regulation. For further information, please contact your local ZOLL representative or send an email to: EUMDR@zoll.com.

Sincerely,

Elizabeth McMeniman

Digitally signed by Elizabeth McMeniman
Date: 2020.10.22 11:01:29 -04'00'

Elizabeth McMeniman
Director, Regulatory Affairs