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An Asahi Kasei Group Company

15 February 2024

Dear Customer:

At ZOLL Medical Corporation, we continue to work diligently toward achieving compliance with the European Regulation (EU) 2017/745, commonly referred to as the European Medical Device Regulation (MDR).

The European Parliament voted to ***adopt an extension*** (CLICK HERE) of the transition period for the EU Medical Device Regulations and to ***extend the validity of certain device certificates*** to provide Notified Bodies with '*more time*' to certify medical devices under EU MDR due to capacity constraints.

Key Changes Include:

- Extend the transitional period for higher-risk devices (class III & certain class IIb implantables) to comply with EU MDR requirements until **31 December 2027**
- Extend the transitional period for medium and lower-risk devices (other class IIb devices, class IIa, class Im, Is and Ir devices) to comply with EU MDR requirements until **31 December 2028**

ZOLL recently received MDR Approval for **ZOLL AED 3** - ZOLL AED 3 defibrillators are now MDR compliant - ZOLL Medical and anticipates approval for **AED Plus** to follow as all rounds of review have been completed.

The following devices are also ***under review*** with our Notified Body:

- ZOLL M2
- AutoPulse NXT
- Powerheart G5
- X Series, X Series Advanced, PPMD
- R Series
- AED Pro
    - ProPaq M – *submission planned in FY24*
    - Ventilators – *submission planned in FY24*
    - Patient Circuits – *submission planned in FY24*
    - Internal Handles – *submission planned in FY24*
    - External Paddles – *submission planned in FY24*

ZOLL is working with their Notified Body to secure an MDD certificate extension letter for all devices that have not obtained MDR approval by the 26 May 2024 (current expiration date of existing CE Certificate).

For further information, please contact your local ZOLL representative or send an email to: EUMDR@zoll.com.

For and on behalf of
ZOLL Medical Corporation

Natalie England

Digitally signed by Natalie England
Date: 2024.02.15 10:26:16 Z

Natalie England
Director, Regulatory Affairs (Regional Lead: EMEA)