defibtech 741 Boston Post Road Suite 201 Guilford, CT 06437 v: 203.453.6654

DEFIBTECH'S EU MDR 2017/745 TRANSITION PLAN

May 07, 2024

Dear Valued Distributor Partners,

The new EU (European Union) MDR (Medical Device Regulations 2017/745) is replacing the existing MDD (Medical Device Directive) 93/42/EEC. The purpose of this communication is to provide information regarding the continued validity of Defibtech's MDD approved devices during the extended transition period between MDD and MDR.

The extension of the transitional period and the concomitant extension of the certificate's validity is done automatically by law, provided the conditions laid down in Article 120(3c) MDR are fulfilled.

Defibtech's devices that are currently approved under the Medical Device Directive (MDD) consist of the following products:

- DDU-100 Automated External Defibrillator
- DDU-120 Automated External Defibrillator
- DDU-2200 Automated External Defibrillator
- DDU-2300 Automated External Defibrillator
- DDU-2400/2450 Automated External Defibrillator
- RMU-1000 Automated Chest Compressor

Per EU MDR 2017/745 Article 120, manufacturers may continue to sell MDD approved products within the European Union if the manufacturer has a contract and a formal application with an MDR notified body for the devices in question. The validity of the MDD approved devices is extended to 31 December 2027 for AEDs and 31 December 2028 for the RMU-1000. These dates are assigned based on device classification in the EU.

Defibtech confirms that the requirements of Article 120 have been met, and the products listed above may continue to be marketed in the EU while MDR and UKCA certification is in progress.

As previously mentioned in our communication to distributor partners in 2019 entitled, "EUROPEAN MEDICAL DEVICE REGULATION COMPLIANCE AGREEMENT 2019", document number DLD-0016-01 Rev. A, information for importers and/or distributors regarding the EU MDR may be found in the EU MDR 2017/745, Chapter II, Article 13 General Obligations of Importers and Article 14 General Obligations of Distributors. * We encourage you to become familiar with these regulations, note the deadlines and monitor the activities for importers/distributors associated with the EU MDR.

* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424

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Defibtech is committed to meeting the expectations of the EU MDR in a timely manner and is well-positioned to transition to these regulations. Compliance to the EU MDR will require cooperative effort on the part of manufacturers, importers, and authorized distributor partners. Defibtech appreciates the help and cooperation of our strategic partners while we transition to these new regulations.

If you should have any questions about this correspondence, please contact salesops@defibtech.com or me, Bob Jamieson, at bjamieson@defibtech.com.

Sincerely,

Robert Jamieson
VP, Quality and Regulatory Affairs

* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424