DECLARATION OF CONFORMITY

Manufacturer: **Defibtech LLC**
741 Boston Post Road, Suite 201
Guilford, CT 06437

Declares that the CE marked product:

Product: **Semi-Automatic External Defibrillator**
Models: **DDU-A2300, DDU-C2300, & DDU-E2300**

Product: **Battery Pack**
Models: **DBP-2003, DBP-2013**

Product: **Defibrillation/Monitoring Pads**
Models: **DDP-2001, DDP-2002**

Complies with all applicable provisions of the Council Directive 93/42/EEC (Medical Device Directive). The technical file required by this Directive is maintained at the Manufacturer site listed above.

Rule 9, Section III (Classification), Annex IX (Classification Criteria) of the Council Directive 93/42 EEC Concerning Medical Device was used to classify the products listed above as Class IIb medical devices following EC conformity path from Annex II, excluding Section 4.

Technical File Reference Document TF-00001 lists all standards that apply.

Valid from 05/25/2021 to 05/26/2024

Notified Body: **0197 – TUV Rheinland LGA Products GmbH**
Tillystraße 2, 90431 Nürnberg Germany

Certification Number: **HD 2218527-1**

European Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Nicole Bush
Vice President, Regulatory Affairs and Quality
Defibtech, LLC

22 July 2021
Date

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