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-100A, DDU-100B, DDU-100C, & DDU-100E**

Product: **Battery Pack**
Models: **DBP-1400, DBP-2800**

Product: **Defibrillation/Monitoring Pads**
Models: **DDP-100, DDP-200P**

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.

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

Valid from 12/03/2018 to 11/07/2023

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

Certification Number: **HD 60133912 0001**

European Authorized Representative:
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Prinsessegracht 20
2514 AP The Hague
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Ed Horton
Vice President, Quality and Regulatory Affairs
Defibtech, LLC

December 3, 2018
Date

ELECTRONIC DISTRIBUTION
DAC-710-BP