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, & DDU-100H

Product:

Battery Pack

Models:

DBP-1400, DBP-2800, & DBP-H2800

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 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

DAC-710-BR