

DECLARATION OF CONFORMITY

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

Declares that the CE marked product:

Product: **Semi-Automatic External Defibrillator**
Model: **DDU-100 Series**

Complies with all applicable provisions of the Council Directive 93/42/EEC (Medical Device Directive)

Product is Class IIb per Rule 9 of the Directive

The following accessories are included in this declaration:

- DBP-1400 Standard Battery Pack
- DBP-2800 High Capacity Battery Pack
- DDP-100 Adult Defibrillation/Monitoring Pads
- DDP-200P Pediatric Defibrillation/Monitoring Pads
- DDC-6, DDC-12, DDC-50AE, DDC-100AE Data cards
- DSU-100 Series Field Update Card

The following standards apply:

- EN 60601-1:1990 +A1:1991 +A2:1995
- EN 60601-1-2:2001 +A1:2006
- EN 60601-1-4:1996 +A1:2000
- EN 60601-2-4:2003
- EN 60601-1-6:2007
- EN 60529:2001 Cor.1:2003
- EN 980:2008
- EN ISO 10993-1:2003
- EN ISO 10993-5:1999
- EN ISO 10993-10:2002 +A1:2006
- EN ISO 14971:2000
- EN 62304:2006
- EN 1041:2008

Notified Body: **0197 – TUV Rheinland Product Safety GmbH**
Am Grauen Stein, D-51105 Köln, Germany

Certification Number: **HD 60026981 0001**

European Authorized Representative:

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Date



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