

EU Declaration of Conformity

DDU-100 AEDs

Document Number: **DAC-713-EN**

Revision: **C**

Legal Manufacturer	<u>Name:</u> Defibtech, LLC <u>Address:</u> 741 Boston Post Road, Suite 201 Guilford, CT 06437 USA <u>Single Registration Number (SRN):</u> US-MF-000012146
EU Authorized Representative	<u>Name:</u> Emergo Europe B.V. <u>Address:</u> Westervoortsedijk 60 6827 AT Arnhem, The Netherlands <u>Single Registration Number (SRN):</u> NL-AR-000000116
Notified Body	<u>Name:</u> BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands <u>Identification Number:</u> 2797

We hereby declare that the medical device(s) specified in this declaration meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices.

Additionally, we hereby declare that the medical device(s) specified in this declaration are in conformity with:

- **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances (Ro HS) in electrical and electronic equipment as amended by **Directive (EU) 2015/863** with additional Annex II substances, with the exceptions of Annex III and of lead solder in portable emergency defibrillators (and their accessories) as allowed for in Annex IV, Exemption 17. Refer to DAC-711-EN-BF for RoHS Declaration of Conformity.
- Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC. Refer to Declaration of Conformity, Battery Regulation (EU) 2023/1542 (DOC-000040 for the DBP-1400 battery and DOC-000041 for the DBP-2800 and DBP-H2800 batteries).

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No Common Specifications were used for declaration of conformity.

This declaration is supported by the Quality System approval to EN ISO 13485:2016 and issued under the sole responsibility of Defibtech, LLC and authorizes Defibtech, LLC to affix the CE-marking to the products listed herein. All supporting documentation is retained at the premises of the manufacturer.

Technical Documentation Summary	TD-00001_DDU-100 AEDs
Conformity Assessment Route - This declaration is made in accordance with relevant Annexes of Regulation (EU) MDR 2017/745, as specified herein:	AED Main Units - Annex IX, Chapters I, II and III Defibrillation/Monitoring pads and Batteries – Annex IX, Chapters I and III
Product Classification	AED Main Units – Class III Defibrillation/Monitoring pads – Class IIb Batteries – Class IIb
Classification Rule	AED Main Units – Rule 22 Defibrillation/Monitoring pads – Rule 9 Batteries – Rule 9
Intended Purpose of the Device	The DDU-100 AEDs are intended to deliver short-duration high-current electrical shock to patients to treat ventricular fibrillation and certain ventricular tachycardias.

Certificate(s) Number	Certificate(s) Type	Expiration
MDSAP 822553	QMS - ISO 13485:2016 Certificate (Annex IX), MDSAP	2027-08-31
MD 822548	QMS – ISO 13485:2016 Certificate	2027-08-31
MDR 781624 R000	Verification for conformity assessment on Technical Documentation (Annex IX, Chapter II)	2029-11-13
MDR 781617 R000	MDR 2017/745 (Annex IX, Chapters I and III)	2029-11-13

AED:

Product Group Name	Product Name (as listed on label)	Basic UDI-DI	GMDN	EMDN
DDU series Semi-automatic AED	DDU-100	081509802DDUE3	47910	Z12030501
DDU series Semi-automatic AED	DDU-100H	081509802DDUE3	47910	Z12030501

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Product Group Name	Product Name (as listed on label)	Basic UDI-DI	GMDN	EMDN
Battery Pack	DBP-1400	081509802DDUE3	38558	Z12030580
Battery Pack	DBP-2800	081509802DDUE3	38558	Z12030580
Battery Pack	DBP-H2800	081509802DDUE3	38558	Z12030580
Defibrillation Electrode	DDP-100	081509802DDUE3	44771	Z12030585
Defibrillation Electrode	DDP-200P	081509802DDUE3	41587	Z12030585

Approvals

Print Name and Designation: (PRRC for Defibtech, LLC)	Robert Jamieson VP, Quality and Regulatory Affairs
Signature:	 Signed by: <i>Bob Jamieson</i> Signer Name: Bob Jamieson Signing Reason: I approve this document Signing Time: 11/18/2025 11:41:42 AM EST 10B90D51E285466A92A2FD043C0D660A
Date of Issue:	11/18/2025
Place of Issue:	Guilford, CT USA

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Document Number: **DAC-713-EN**Revision: **C****Appendix 1: DDU-100 Semi-automatic AED Catalogue Number References**

Catalogue Number (REF)	Product and Language Information
CCF-A008EN	DDU-100 domestic English language, standard capacity battery pack
CCF-A009EN	DDU-100 domestic English language, standard capacity battery pack
CCF-A010EN	DDU-100 domestic English language, high capacity battery pack
CCF-A011EN	DDU-100 domestic English language, high capacity battery pack
CCF-A014EN	DDU-100 domestic English language, standard capacity battery pack
CCF-A015EN	DDU-100 domestic English language, standard capacity battery pack
CCF-A016EN	DDU-100 domestic English language, standard capacity battery pack
CCF-A017EN	DDU-100 domestic English language, high capacity battery pack
CCF-A018EN	DDU-100 domestic English language, high capacity battery pack
CCF-A019EN	DDU-100 domestic English language, high capacity battery pack
CCF-E014CA	DDU-100 export English language, standard capacity battery pack
CCF-E015CA	DDU-100 export English language, standard capacity battery pack
CCF-E016CA	DDU-100 export English language, standard capacity battery pack
CCF-E017CA	DDU-100 export English language, high capacity battery pack
CCF-E018CA	DDU-100 export English language, high capacity battery pack
CCF-E019CA	DDU-100 export English language, high capacity battery pack
CCPRX-0004	DDU-100 domestic English language, standard capacity battery pack
CCPRX-0005	DDU-100 domestic English language, high capacity battery pack
DCF-A100-EN	DDU-100 domestic English language, standard capacity battery pack
DCF-A100-ES	DDU-100 domestic Argentine language, standard capacity battery pack
DCF-A100RX-EN	DDU-100 domestic English language, standard capacity battery pack
DCF-A105-EN	DDU-100 domestic English language, AED only
DCF-A110-EN	DDU-100 domestic English language, high capacity battery pack
DCF-A110-ES	DDU-100 domestic Argentine language, high capacity battery pack
DCF-A110RX-EN	DDU-100 domestic English language, high capacity battery pack
DCF-E100SG-AR	DDU-100 Argentine language, standard capacity battery pack
DCF-E100-CA	DDU-100 export English, standard capacity battery pack
DCF-E100SG-CZ	DDU-100 Czech language, standard capacity battery pack
DCF-E100SG-DE	DDU-100 German language, standard capacity battery pack
DCF-E100SG-DK	DDU-100 Danish language, standard capacity battery pack
DCF-E100SG-EN	DDU-100 English language, standard capacity battery pack
DCF-E100SG-FR	DDU-100 French language, standard capacity battery pack
DCF-E100SG-HK	DDU-100 traditional Chinese, standard capacity battery pack
DCF-E100SG-HR	DDU-100 Croatian language, standard capacity battery pack
DCF-E100SG-IL	DDU-100 Hebrew language, standard capacity battery pack
DCF-E100SG-IT	DDU-100 Italian language, standard capacity battery pack
DCF-E100SG-KR	DDU-100 Korean language, standard capacity battery pack
DCF-E100SG-NL	DDU-100 Dutch language, standard capacity battery pack
DCF-E100SG-NO	DDU-100 Norwegian language, standard capacity battery pack
DCF-E100SG-PL	DDU-100 Polish language, standard capacity battery pack
DCF-E100SG-SE	DDU-100 Swedish language, standard capacity battery pack

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DCF-E100SG-SI	DDU-100 Slovenian language, standard capacity battery pack
DCF-E100SG-SP	DDU-100 Spanish language, standard capacity battery pack
DCF-E100SG-TH	DDU-100 Thai language, standard capacity battery pack
DCF-E100SG-UK	DDU-100 British English, standard capacity battery pack
DCF-E100-TW	DDU-100 Taiwan voice, standard capacity battery pack
DCF-E105SG-AR	DDU-100 Argentine language, AED only
DCF-E105-CA	DDU-100 English language, AED only
DCF-E105SG-CF	DDU-100 French language, AED only
DCF-E105SG-CZ	DDU-100 Czech language, AED only
DCF-E105SG-DE	DDU-100 German language, AED only
DCF-E105SG-DK	DDU-100 Danish language, AED only
DCF-E105SG-EN	DDU-100 English language, AED only
DCF-E105SG-FR	DDU-100 French language, AED only
DCF-E105SG-HK	DDU-100 traditional Chinese, AED only
DCF-E105SG-HR	DDU-100 Croatian language, AED only
DCF-E105SG-IL	DDU-100 Hebrew language, AED only
DCF-E105SG-IT	DDU-100 Italian language, AED only
DCF-E105SG-KR	DDU-100 Korean language, AED only
DCF-E105SG-NL	DDU-100 Dutch language, AED only
DCF-E105SG-NO	DDU-100 Norwegian language, AED only
DCF-E105SG-PL	DDU-100 Polish language, AED only
DCF-E105SG-SE	DDU-100 Swedish language, AED only
DCF-E105SG-SI	DDU-100 Slovenian language, AED only
DCF-E105SG-SP	DDU-100 Spanish language, AED only
DCF-E105SG-TH	DDU-100 Thai language, AED only
DCF-E105SG-UK	DDU-100 British English, AED only
DCF-E105-TW	DDU-100 Taiwan voice, AED only
DCF-E110SG-AR	DDU-100 Argentine language, high capacity battery pack
DCF-E110SG-CF	DDU-100 French language, high capacity battery pack
DCF-E110SG-CZ	DDU-100 Czech language, high capacity battery pack
DCF-E110SG-DK	DDU-100 Danish language, high capacity battery pack
DCF-E110SG-EN	DDU-100 English language, high capacity battery pack
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DCF-E110SG-IT	DDU-100 Italian language, high capacity battery pack
DCF-E110SG-NL	DDU-100 Dutch language, high capacity battery pack
DCF-E110SG-NO	DDU-100 Norwegian language, high capacity battery pack
DCF-E110SG-PL	DDU-100 Polish language, high capacity battery pack
DCF-E110SG-SE	DDU-100 Swedish language, high capacity battery pack
DCF-E110SG-SI	DDU-100 Slovenian language, high capacity battery pack
DCF-E110SG-SP	DDU-100 Spanish language, high capacity battery pack
DCF-E110-CA	DDU-100 export English, high capacity battery pack
DCF-E110-CF	DDU-100 export French, high capacity battery pack
DCF-E110SG-HK	DDU-100 traditional Chinese, high capacity battery pack
DCF-E110SG-HR	DDU-100 Croatian language, high capacity battery pack
DCF-E110SG-IL	DDU-100 Hebrew language, high capacity battery pack

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DCF-E110SG-UK	DDU-100 British English, high capacity battery pack
DCF-E110-TW	DDU-100 Taiwan voice, high capacity battery pack
DCF-H110SG-IL	DDU-100 Hebrew language, high capacity battery pack, Hatzalah