



**Certificate No. 3214-1-2025-2**

**CERTIFICATE TO FOREIGN GOVERNMENT**

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from January 09, 2025 to January 08, 2027.**



To verify the authenticity of the information on this certificate, you may scan the QR code or visit [www.access.fda.gov/fecv/CDRH](http://www.access.fda.gov/fecv/CDRH).



**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

**Certificate No. 3214-1-2025-2**

**Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1**

**Name of Corporate Headquarters**

DEFIBTECH, LLC  
741 BOSTON POST ROAD  
SUITE 201  
Guilford, CT  
USA 06437

**Name of Manufacturer**

**Manufacturer**

DEFIBTECH, LLC  
741 BOSTON POST ROAD, SUITE 201  
GUILFORD, CT  
USA 06437

**Manufacturing Facility**

Defibtech Branford  
14 Commercial St  
Branford, CT  
USA 06405

----END OF MANUFACTURER/DISTRIBUTOR LIST----





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**Name of Manufacturer**

**Manufacturer**

DEFIBTECH, LLC  
741 BOSTON POST ROAD, SUITE 201  
GUILFORD, CT  
USA 06437

**Manufacturing Facility**

Defibtech Branford  
14 Commercial St  
Branford, CT  
USA 06405

**Name of Product(s)**

AUTOMATED EXTERNAL, DEFIBRILLATOR (AED)  
DDU-100E lifeline Defibrillator AED and related accessories  
DDU-100E Lifeline Defibrillator AED  
DDU-120E Lifeline AUTO Defibrillator AED and related accessories  
DDU-120E Lifeline AUTO Defibrillator AED  
DDU-E2200 VIEW AUTO Automatic External Defibrillator  
DDU-E2200 VIEW AUTO Automatic External Defibrillator and Accessories  
DDU-E2300 Lifeline VIEW Defibrillator AED and related accessories  
DDU-E2300 Lifeline VIEW Defibrillator AED  
DDU-E2450 Lifeline ECG Defibrillator AED and related accessories  
DDU-E2450 Lifeline ECG Defibrillator AED  
DBP-2009 Battery Pack  
DBP-1400 (Battery Pack)  
DBP-2800 (Battery Pack)  
DDP-100 (Defibrillation Pads)  
DDP-200P (Defibrillation Pads)  
DBP-2003 (Battery Pack)  
DBP-2013 (Battery Pack)  
DDP-2001 (Defibrillation Pads)  
DDP-2002 (Defibrillation Pads)  
DBC-2001 Battery Pack Charging Stand  
AUTOMATED CHEST COMPRESSOR {ACC}  
RMU-E1000 Automated Chest Compressor and related accessories  
RMU-E1000 Automated Chest Compressor  
RPM-1000 {External AC Power Adapter}  
RPM-2000 {External AC Power Adapter}  
RBP-1000 (Battery Pack)  
RMF-1000 (Frame)  
RPP-1000 (Patient Interface Pads)  
RAC-1600 Defibtech ACC Event Connect  
RBC-1000 Charging Stand and Wall Charger

-----END OF PRODUCT LIST-----

