



Certificate No. 14393-9-2020

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.

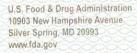
Sincerely,

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 September 17, 2020 to September 16, 2022.







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Name of Corporate Headquarters

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

Name of Manufacturer

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

Contract Manufacturer

ANSEN CORPORATION 100 CHIMNEY POINT DR. Ogd, NY USA 13669

Manufacturing Facility

Defibtech Branford 14 Commercial St Branford, CT USA 06405

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





U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

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Name of Product(s)

DBC-2001 Battery Pack Charging Stand RAC-1600 Defibtech ACC Event Connect

DDU-E2200 VIEW AUTO Automatic External Defibrillator

DDU-E2200 VIEW AUTO Automatic External Defibrillator and Accessories

RBC-1000 Charging Stand and Wall Charger

DBP-2009 Battery Pack

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

DBP-1400 (Battery Pack)

DBP-2800 (Battery Pack)

DDP-100 (Defibrillation Pads)

DDP-200P (Defibrillation Pads)

DAC-300E (Adapter)

DAC-310E (Adapter)

RMU-E1000 Automated Chest Compressor and related accessories

RMU-E1000 Automated Chest Compressor

RPM-1000 (External AC Power Adapter)

RBP-1000 (Battery Pack)

RMF-1000 (Frame)

RPP-1000 (Patient Interface Pads)

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-2003 (Battery Pack)

DBP-2013 (Battery Pack)

DDP-2001 (Defibrillation Pads)

DDP-2002 (Defibrillation Pads)

DAC-2000 (Adapter)

DAC-2010 (Adapter)

END OF PRODUCT LIST-----

