

Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Certificate No. 799-10-2016

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)

Name of Manufacturer/Distributor, Address

See Attached List

See Attached List

(Two Pages)

(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.

Carl Fischer, Ph.D.

Caro

Director

Division of International Compliance Operations

Office of Compliance

Center for Devices and Radiological Health

This certificate is valid from October 24, 2016 to October 23, 2018.





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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

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

Manufacturing Facility

DEFIBTECH, LLC 4 PROGRESS AVENUE SEYMOUR, CT USA 06483

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----





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Certificate No. 799-10-2016 Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2 Name of Corporate Headquarters

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Contract Manufacturer

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

Manufacturing Facility

Defibtech Branford 14 Commercial St Branford, CT USA 06405

Name of Product(s)

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)

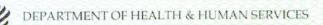
DDP-2002 (Defibrillation Pads)

DAC-2000 (Adapter)

DAC-2010 (Adapter)

DAC-2020 (ECG Monitoring Cable)





Public Health Service

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DAC-2021E (ECG Monitoring Cable)
DMP-2403 (ECG Monitoring Electrodes)
DAC-420 (Rescue Pack)

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

