

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez, PhD

3. acting in the capacity of Director, DRP2: Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twentieth of February, 2020

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 20021861-15

9. Seal/Stamp:

10. Signature:



Leo J Muldoon

Certificate No. 1596-11-2019

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 November 08, 2019 to November 07, 2021.



Montana 169163

Certificate No. 1596-11-2019
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator
CARDIAC SCIENCE CORPORATION
500 Burdick Parkway
Deerfield, WI USA 53531

Name of Manufacturer/Distributor
CARDIAC SCIENCE CORPORATION
500 Burdick Pkwy
DEERFIELD, WI USA 53531

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



Permit No. 1596-11-2019

Permit to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

GARDIAC SCIENCE CORPORATION
500 Burdick Parkway
Deerfield, WI USA 53531

Name of Manufacturer/Distributor

GARDIAC SCIENCE CORPORATION
500 Burdick Pkwy
DEERFIELD, WI USA 53531

Name of Product(s)

- Powerheart G3 Plus Automated External Defibrillator (Automatic) - 9390A-XXXX
 - Powerheart G3 Plus Automated External Defibrillator (Semi Automatic) - 9390E-XXXX
 - Powerheart G3 Pro Automated External Defibrillator - 9300P-XXXX
 - G3 Polarized Defibrillation Pads/Electrodes - 9660
 - G3 Defibrillation Pads/Electrodes - 9131
 - G3 Pediatric Defibrillation Pads/Electrodes - 9730
- END OF PRODUCT LIST-----

