



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

Certificate No. 13808-8-2019

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 August 28, 2019 to August 27, 2021.





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

Name of Owner Operator

INFINIUM MEDICAL, INC.
12151 62ND ST N
UNIT 5
Largo, FL USA 33773

Name of Manufacturer

Manufacturer
INFINIUM MEDICAL, INC.
12151 62ND ST., N,
UNIT 5
Largo, FL USA 33773

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





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Name of Product(s)

OMNI III Patient Monitor

OMNI Express Patient Monitor

ATS Operating Table

OMNI II Patient Monitor

OMNI Patient Monitor

QRS 12 Electrocardiograph

ADS II Anesthesia Delivery System

ClearVue Video Laryngoscope

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

