



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

Certificate No. 3071-12-2021

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 December 27, 2021 to December 26, 2023.





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

Name of Corporate Headquarters

IVY BIOMEDICAL SYSTEMS, INC.
11 BUSINESS PARK DR.
Branford, CT
USA 06405

Name of Manufacturer/Distributor

IVY BIOMEDICAL SYSTEMS, INC.
11 BUSINESS PARK DR.
Branford, CT
USA 06405

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





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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Name of Manufacturer/Distributor

IVY BIOMEDICAL SYSTEMS, INC.

11 BUSINESS PARK DR.

Branford, CT

USA 06405

Name of Product(s)

Models 7600, 7700, 7800 Cardiac Trigger Monitor

Models 7600EP, 7800EP Cardiac Trigger Monitor

Model 7810 Cardiac and Respiratory Trigger Monitor

Models 3000, 3150 Cardiac Trigger Monitor

CTM-300, UPMM Cardiac Trigger Module

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

