



**Certificate No. 13587-9-2023**

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 06, 2023 to September 05, 2025.**





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

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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----





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

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Branford, CT  
USA 06405

**Name of Manufacturer/Distributor**

IVY BIOMEDICAL SYSTEMS, INC.  
11 BUSINESS PARK DR.  
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**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, CTM-400, CTM-500/502, UPMM, UPMM-X Cardiac Trigger Module  
Model WGS-100, MR Wireless Gating System  
MRI PPG Patient Cable  
MRI ECG Patient Cable  
-----END OF PRODUCT LIST-----

