

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

Certificate No. 66-12-2012

#### 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

Name of Manufacturer/Distributor IVY BIOMEDICAL SYSTEMS, INC. 11 BUSINESS PARK DR. **BRANFORD CT USA 06405** 

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.

Ann M. Ferriter

Director

Division of Risk Management Operations

Office of Compliance

Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY STATE OF MARYLAND

Subscribed and sworn to before me this

day of December

CATHRYN N. MORRIS NOTARY PUBLIC STATE OF MARYLAND County of Montgomery My Commission Expires January 4, 2013





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Certificate No. 66-12-2012 Certificate to Foreign Government - Name of Products Attachment Page 1 of 1

# Name of Manufacturer/Distributor IVY BIOMEDICAL SYSTEMS, INC.

11 BUSINESS PARK DR. --BRANFORD, CT, USA 06405

#### Name of Products

Models 7600, 7800-Physiological Monitor for ECG & Trigger Monitor
Models 3000, 3150-Physiological Monitor for ECG & Trigger Monitor
Model 6000-Physiological Monitor for SpO2 & ETC02
Model 450C-Physiological Monitor for ECG, Resp., Temp., IBP, NIBP, SpO2, ETC02
------END OF PRODUCTS LIST-------

