



**Certificate No. 7511-3-2017**

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)**

ThunderBolt EIA/EIA-CL ELISA ANALYZER

**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.

Robin W. Newman MSN EdD CPNP  
Director  
Office of Compliance  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from March 30, 2017 to March 29, 2019.**

