



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

**Certificate No. 3320-12-2018**

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
ThunderBolt EIA/EIA-CL ELISA ANALYZER	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.

CAPT Sean M. Boyd, MPH, USPHS  
Deputy Director for Regulatory Affairs  
Office of Compliance  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from January 10, 2019 to January 09, 2021.**





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

**Name of Owner Operator**

Gold Standard Diagnostics  
2851 spafford street  
Davis, CA USA 95618

**Name of Manufacturer**

GOLD STANDARD DIAGNOSTICS CORP.  
2851 spafford street  
Davis, CA USA 95618

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

