



Certificate No. 5424-7-2015

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> |
|--------------------------------------|--|
| See Attached List<br><br>(Two Pages) | See Attached List<br><br>(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.

Carl Fischer, Ph.D.  
Director  
Division of International Compliance Operations  
Office of Compliance  
Center for Devices and Radiological Health

This certificate is valid from July 15, 2015 to July 14, 2017.





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

**Name of Owner Operator**

ACON Laboratories, Inc.  
10125 Mesa Rim Road  
San Diego, CA USA 92121

**Name of Manufacturer/Distributor**

ACON LABORATORIES, INC.  
10125 Mesa Rim Road  
SAN DIEGO, CA USA 92121

**Name of Manufacturer**

ACON BIOTECH (HANGZHOU) CO., LTD.  
No. 210 Zhenzhong Road  
West Lake District  
HANGZHOU, Zhejiang CHINA 310030

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





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**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2**

**Name of Owner Operator**

ACON Laboratories, Inc.  
10125 Mesa Rim Road  
San Diego, CA USA 92121

**Name of Manufacturer/Distributor**

ACON LABORATORIES, INC.  
10125 Mesa Rim Road  
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**Name of Manufacturer**

ACON BIOTECH (HANGZHOU) CO., LTD.  
No. 210 Zhenzhong Road  
West Lake District  
HANGZHOU, Zhejiang CHINA 310030

**Name of Product(s)**

On Call® Plus Blood Glucose Monitoring System G113-111  
On Call® Plus Blood Glucose Meter G113-112, G113-113, G113-216  
On Call® Plus Blood Glucose Meter G113-211, G113-214  
On Call® Plus Blood Glucose Test Strips G133-111, G133-112, G133-114  
On Call® Plus Blood Glucose Test Strips G133-115, G133-118, G133-211  
On Call® Plus Glucose Control Solution G123-311  
On Call® Plus Lancing Device G123-211  
On Call® Plus Lancets G123-111  
On Call® Lancing Device G124-11A  
On Call® Lancets G124-10A  
Mission® Lancing Device G121-3051  
Mission® Lancets G121-3041  
On Call® Safety Lancet II G123-8B1  
Mission® Safety Lancet II C121-3071  
On Call Gentouch® Lancing Device G124-17A  
On Call Stealth® Lancing Device G124-18A  
On Call® Plus Diabetes Monitoring Software G123-511  
On Call® Chosen Blood Glucose Monitoring System G114-106  
On Call® Chosen Blood Glucose Meter G114-116, G114-126, G114-236  
On Call® Chosen Blood Glucose Test Strips G134-106, G134-116  
On Call® Chosen Glucose Control Solution G124-126  
On Call® Vivid Blood Glucose Monitoring System G115-102  
On Call® Vivid Blood Glucose Meter G115-112, G115-122, G115-132  
On Call® Vivid Blood Glucose Test Strips G135-102, G135-112  
On Call® Vivid Glucose Control Solution G125-122  
On Call® Vivid Pal Blood Glucose Monitoring System G115-107  
On Call® Vivid Pal Blood Glucose Meter G115-117, G115-127, G115-137  
On Call® Vivid Pro Blood Glucose Monitoring System G115-118  
On Call® Vivid Pro Blood Glucose Meter G115-118  
On Call® Vivid Pro Blood Glucose Test Strips G135-105, G135-118  
On Call® Vivid Pro Glucose Control Solution G125-128  
Mission® U120 Urine Analyzer U111-101, U111-111  
Mission® U120 Ultra Urine Analyzer U114-101, U114-111  
Insight U120 Urine Analyzer U111-105, U111-115  
Foresight™ U120 Urine Analyzer U111-103, U111-113  
Mission® U500 Urine Analyzer U211-101, U211-111  
Insight U500 Urine Analyzer U211-105, U211-115  
ACON™ UTI Urinary Tract Infection Test Strips U031-025  
Mission® UTI Urinary Tract Infection Test Strips U031-021  
Insight Urinalysis Reagent Strips Various  
Mission Urinalysis Reagent Strips Various





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**Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2**

Mission Urinalysis Reagent Strips (Microalbumin/Creatinine) Various  
Mission® Liquid Urine Control U021-011, U021-021, U021-031  
Mission® Liquid Diptube Urine Control U021-071, U021-081, U021-091  
Mission® Dry Strip Urine Control U021-041, U021-051, U021-061  
Mission® Breath Alcohol Detector U031-011, U031-031  
Mission® Saliva Alcohol Test Strip C031-021  
Mission® Plus Hemoglobin (Hb) Testing System C112-3041  
Mission® Plus Hemoglobin (Hb) Meter C112-3061, C112-3051  
Mission® Plus Hemoglobin (Hb) Test Cartridges C132-3021, C132-3041  
Mission® Plus Hemoglobin (Hb) Optical Verifiers C122-3021  
Mission® Plus Hemoglobin (Hb) Control Solution C122-3041  
Mission® Capillary Transfer Tubes C121-2081  
Mission® Adapter Kit C121-3011  
On Call® Express Blood Glucose Monitoring System G115-10D  
On Call® Express Blood Glucose Meter G115-11D  
On Call® Express Blood Glucose Test Strips G135-10D, G135-11D  
On Call® Express Glucose Control Solution G125-12D  
On Call® Extra Blood Glucose Monitoring System G115-11H  
On Call® Extra Blood Glucose Meter G115-10H, G115-12H, G115-13H  
On Call® Extra Blood Glucose Test Strips G135-10H, G135-11H  
On Call® Extra Glucose Control Solution G125-12H  
On Call® Sharp Blood Glucose Monitoring System G115-105  
On Call® Sharp Blood Glucose Meter G115-115, G115-125, G115-135  
On Call® Sharp Blood Glucose Test Strips G135-105, G135-115  
On Call® Sharp Glucose Control Solution G125-125  
On Call® Diabetes Management Software G124-13A

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

