



Certificate No. 3040-4-2015

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:

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.

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

This certificate is valid from April 29, 2015 to April 28, 2017.





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

Name of Manufacturer

JAS Diagnostics/Drew Scientific
14100 N.W. 57th Court
Miami Lakes, FL USA 33014

R & D SYSTEMS, INC.
614 MCKINLEY PL., N.E.
MINNEAPOLIS, MN USA 55413

BIT Group USA, Inc.
15870 Bernardo Center Dr
SAN DIEGO, CA USA 92127

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





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

Name of Manufacturer

JAS Diagnostics/Drew Scientific
14100 N.W. 57th Court
Miami Lakes, FL USA 33014

Name of Product(s)

Cat# DREW3-PAC: Drew3 Reagent Pack
Cat# DREW3-PAC-CNF: Drew3 Reagent Pack Cyanide Free

Name of Manufacturer

R & D SYSTEMS, INC.
614 MCKINLEY PL., N.E.
MINNEAPOLIS, MN USA 55413

Name of Product(s)

Cat# EXA-326: EX-TROL Hematology Control Kit
Cat# EXA-346: EX-TROL Hematology Control Kit
Cat# EXA-25L/EXA-25N/EXA-25H: Hematology Controls (L, N,H)
Cat# EXA-45L/EXA-45N/EXA-45H: Hematology Controls (L, N,H)
Cat# CA-30X: EX-CAL Hematology Calibrator

Name of Manufacturer

BIT Group USA, Inc.
15870 Bernardo Center Dr
SAN DIEGO, CA USA 92127

Name of Product(s)

Cat# BAR-9001-181: DREW3 Hematology Analyzer

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

