



Certificate No. 6411-6-2016

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

(Two Pages)

Name of Manufacturer/Distributor, AddressName of ManufacturerR & D SYSTEMS, INC.
614 MCKINLEY PL., N.E.
MINNEAPOLIS, MN USA 55413

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 12, 2016 to July 11, 2018.





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Name of Manufacturer

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

Name of Product(s)

AMP Hemotrol 16 Control
BCI AcT 5diff Cal Calibrator
BCI AcT 5diff Control Plus
BCI Leuko-Trol PLT Control
BCI Leuko-Trol RBC Control
BD Multi-Check CD4 Low Control
BD-Multi-Check Control
BD Retic-Count Control
BD Leukocount PLT Control
BD Leukocount RBC Control
BD Stem Cell Control
Bio-Rad Retic Control A-I
Bio-Rad Liquichek Hematology 16T Control
Bio-Rad Liquichek Hematology Control A
Bio-Rad Liquichek Hematology Control C
Bio-Rad Liquichek Hematology Control X
Desse ESR Control
Drew Ex-Cal
Drew MD-Cal
Drew Ex-Trol
Horiba Erytrol
Horiba Difftrol Control
Horiba LC-REF Calibrator
Horiba LC-Trol 8 Control
Horiba LC-Trol 16 Control
Horiba LC-Trol 16P Control
Horiba LC-Trol 20 Control
Horiba LC-Trol CRP Control
Horiba LC-Trol R5 Control
Horiba MINOCAL Calibrator
Horiba MINOTROL 8 Calibrator
Horiba MINOTROL 16 Calibrator
Horiba MINOTROL CRP Calibrator
Horiba MINOTROL RETIC Control
Mindray BC-RET
Mindray SC-CAL PLUS Calibrator
Nihon Kohden MEK-CAL
Nihon Kohden MEK-3D
Orphee Myt-3D Control
Orphee Myt-CAL Control
QBC Hematology Control
R&D 3K Retic Control
R&D 4K Retic Control
R&D Advia Retic Plus Control
R&D Body Fluid Control
R&D Body Fluid-I Control
R&D FetalTrol
R&D CBC-3D Control
R&D CBC-3D for Diamond Control
R&D CBC-3D for Mindray
R&D CBC-3D+CRP Control
R&D CBC-3K Control





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R&D CBC-5D Control
R&D CBC-7 Control
R&D CBC-7 HemoCue Control
R&D CBC-8 Control
R&D CBC-Cal Plus Calibrator
R&D CBC-LINE for Hemocue Linearity Kit
R&D CBC-LINE Linearity Kit
R&D CBC-LINE Low Range Linearity Kit
R&D CBC-LINE PLT Linearity Kit
R&D CBC-LINE RBC Linearity Kit
R&D CBC-LINE WBC Linearity Kit
R&D CBC-LINE Ultra Low Range Linearity Kit
R&D CBC-LINE Ultra Low Plus RBC Linearity Kit
R&D CBC-ST Plus
R&D CBC-SYS Control
R&D CBC-Tech Control
R&D CBC-X Control
R&D CD-Cal Calibrator
R&D CSF Automated Control
R&D GluHgb Whole Blood Control
R&D GLU-LINE Linearity Kit
R&D HC WBC Control
R&D HCT Extended Control
R&D HGB Extended Control
R&D Leuko-Reduced RBC Control
R&D Leuko-Reduced PLT Control
R&D LH-nRBC Control
R&D NEK-Cal Calibrator
R&D Platelet Trol II Control
R&D Platelet-Trol Extended Control
R&D PLT-LINE Linearity Kit
R&D Retic Control
R&D Retic-I Control
R&D Retic-I Plus Control
R&D RET-LINE Linearity Kit
R&D RET-LINE B Reticulocyte Linearity Kit
R&D SEDRite III Control
R&D SEDRite Plus Control
R&D Sickle QC
R&D StatusFlow Control
R&D StatusFlow Lo Control
R&D StatusFlow Pro Control
R&D Tech-Cal Calibrator
R&D XERet Control
Quantikine IVD Erythropoietin ELISA Kit
Quantikine Erythropoietin Control
Quantikine IVD Erythropoietin ELISA Kit
Quantikine IVD B2 Microglobulin Kit
Quantikine IVD Human Soluble Transferrin Receptor ELISA Kit

END OF PRODUCT LIST

