



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

Certificate No. 6956-2-2018

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:

Name of Product(s)

See Attached List

(Two Pages)

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.

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 March 26, 2018 to March 25, 2020.





U.S. FOOD & DRUG
ADMINISTRATION

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Name of Manufacturer

BECTON, DICKINSON & CO.
7 LOVETON CIR.
SPARKS, MD USA 21152

Name of Distributor

Legal Manufacturer and Distributor

BECTON, DICKINSON & CO.
7 LOVETON CIR.
SPARKS, MD USA 21152

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





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

Name of Manufacturer

BECTON, DICKINSON & CO.
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Name of Distributor

Legal Manufacturer and Distributor

BECTON, DICKINSON & CO.
7 LOVETON CIR.
SPARKS, MD USA 21152

Name of Product(s)

211918 BD MicroProbe™ Processor (220 V)
245015 BD BBL™ CrystalSpec™ Calibration Tubes
246004 BD Phoenix™ AST Indicator Solution
246006 BD Phoenix™ AP AST Indicator Solution
246009 BD Phoenix™ AST-S Indicator Solution
250100 BD MicroProbe™ Processor (120 V)
250107 BD MicroProbe™ Processor
260457 BD BBL™ Single Disc Dispenser
260459 BD BBL™ Single Disc Dispenser
260669 BD BBL™ Sensi-Disc™ 12-Place Dispenser Cannister
271056 BD BBL™ Venting Unit
440478 BD ProbeTec™ ET Instrument, U.S.
440716 BD ProbeTec™ ET Instrument, Remanufactured
440887 BD EpiCenter™ Plus Microbiology Data Management System
441007 BD EpiCenter™ Single User Software
441010 BD BBL Crystal™ MIND Software
441091 BD Viper™ System
441385 BD BACTEC™ FX, Instrument Top, Packaged
441386 BD BACTEC™ FX, Instrument Bottom, Packaged
441743 BD BACTEC™ MGIT™ 320 System
441863 BD™ Innova
441916 BD MAX™ System, BD MAX™ Instrument
441927 BD MAX™ Instrument, Remanufactured
442296 BD BACTEC™ FX40 Instrument
442839 BD Viper™ LT System
442843 BD Viper™ System, Remanufactured
442950 BD Pre-Warm Heater
442958 BD Viper™ LT System SDA Accessory Kit
443624 BD Phoenix™ M50 Automated Microbiology System
445569 BD BACTEC™ 9240, Remanufactured
445702 BD BACTEC™ 9120, Remanufactured
445800 BD BACTEC™ 9050 System
445870 BD BACTEC™ MGIT™ 960 System
445915 BD BACTEC™ 9050, Remanufactured
447161 BD BACTEC™ MGIT™ 960 System, Remanufactured
448007 BD Phoenix™ NID
448008 BD Phoenix™ PID
448100 BD Phoenix™ Automated Microbiology System
448105 BD Phoenix™ Automated Microbiology System, Remanufactured
448316 BD Phoenix™ Yeast ID
448484 BD Phoenix™ NMIC-133
448486 BD Phoenix™ NMIC-304
448487 BD Phoenix™ NMIC-303
448721 BD Phoenix™ NMIC/ID-121
448741 BD Phoenix™ NMIC/ID-302
448742 BD Phoenix™ NMIC/ID-301





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

448743 BD Phoenix™ NMIC/ID-304
448744 BD Phoenix™ NMIC/ID-303
448802 BD Phoenix™ SMIC/ID-101
448803 BD Phoenix™ SMIC-101
448871 BD Phoenix™ NMIC-300

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

