



Certificate No. 13187-9-2022

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.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 09, 2022 to September 08, 2024.





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

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

Name of Manufacturer

BIOMERIEUX, INC.
100 RODOLPHE ST
DURHAM, NC
USA 27712

BIOMERIEUX, INC.
595 ANGLUM RD.
HAZELWOOD, MO
USA 63042

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





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Name of Manufacturer

BIOMERIEUX, INC.
595 ANGLUM RD.
HAZELWOOD, MO
USA 63042

Name of Product(s)

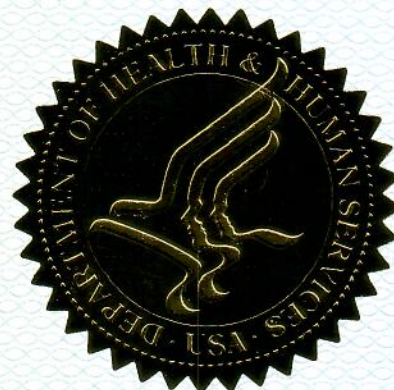
Vitek 2 compact - Ref # 27415
Vitek 2 compact - Ref # 27530
Vitek 2 compact - Ref # 27560
Vitek 2 - Ref # 27226
Vitek 2 - Ref # 27228
VITEK 2 SYSTEMS (PC) SOFTWARE
KIT UPDT VTK2 9.01 EN - Ref# 423011
KIT UPDT VTK2 09.01/09.02 Ref# 423487
KIT UPDT VTK2 9.02 Ref# 423272
DVD SOFTWARE V2S 9.01 Ref# 423428
KIT VTK RP5810 9.02 MEDIA Ref# 423009
KIT VITEK 2 FLEXPREP Dongle Ref# 423059
DVD SOFTWARE V2S 09.02 Ref # 423170
KIT VTK PC-XPRO 9.02 MEDIA - Ref #423852
DensiCHEK Plus - Ref # 21250
DensiCHEK Plus Standards Kit - Ref # 21255
VITEK® DENSICHEK® Pod - Ref # 423000
VITEK® DENSICHEK® Display Base Kit - Ref # 422220
VITEK® DENSICHEK® Connectivity Base - Ref # 422221
BacT/Alert 3D60 - Ref # 248009
BacT/Alert 3D Right Combination Module - Ref # 200290
BacT/Alert 3D Left Combination Module - Ref # 200291
BacT/Alert 3D Control Module - Ref # 210147
BacT/Alert 3D Right Incubation Module - Ref # 210161
BacT/Alert 3D Left Incubation Module - Ref # 210159
BacT/Alert VIRTUO Microbial Detection System - Ref # 411660
BacT/Alert VIRTUO Microbial Detection System R2.0 - Ref # 411661
KIT VIRTUO INST REL 2.0 W/SEC MEDIA EN - Ref # 423266
KIT BacT/ALERT VIRTUO INST REL 2.0 Media Kit EN - Ref # 421114
KIT BacT/ALERT VIRTUO UPDATE 2.0 Media Kit EN - Ref # 421115
BacT/Alert VIRTUO Microbial Detection System (Firmware):
KIT UPDT VIRTUO REL 3.0 EN - Ref 423323
VIRTUO FW UPDT R3.0 - Ref 423376
KIT VIRTUO INST REL 3.0 MEDIA EN - Ref 423378
KIT UPDT VIRTUO REL 3.0 ML - Ref 423559
KIT INST UPDT B.50 ZIP EN - Ref # 420780
KIT INST UPDT B.50 USB EN - Ref # 420781

Name of Manufacturer

BIOMERIEUX, INC.
100 RODOLPHE ST
DURHAM, NC
USA 27712

Name of Product(s)

BacT/Alert MP Reagent System - Ref # 419744
BacT/Alert FA Culture Bottle - Ref # 259791
BacT/Alert FN Culture Bottle - Ref # 259793
BacT/Alert PF Culture Bottle - Ref # 259794
BacT/Alert SA Culture Bottle - Ref # 259789
BacT/Alert SN Culture Bottle - Ref # 259790





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BacT/Alert MP Culture Bottle - Ref # 259797

MAS Mycobacteria Antibiotic Supplement - Ref # 259760

BacT/Alert FA Plus Culture Bottle - Ref # 410851

BacT/Alert FN Plus Culture Bottle - Ref # 410852

BacT/Alert PF Plus Culture Bottle - Ref # 410853

VITEK 2.0 0.45% Sodium Chloride Diluent - Ref # 417820

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

