



Certificate No. 4120-1-2023

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.

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 January 30, 2023 to January 29, 2025.





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

Name of Owner Operator

Bialex Lab
717 Ohio Ave
Wichita Falls, TX
USA 76301

Name of Manufacturer

BIALEX LAB
717 Ohio Ave
Wichita Falls, TX
USA 76301

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





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 Product(s) Attachment Page 1 of 1

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717 Ohio Ave
Wichita Falls, TX
USA 76301

Name of Manufacturer

BIALEX LAB
717 Ohio Ave
Wichita Falls, TX
USA 76301

Name of Product(s)

Bialex Diazo Total & Direct Bilirubin
Bialex Ammonia
Bialex Passcheck Multicontrol Level I & II
Bialex Ecstasy
Bialex Lipase Kinetic
Bialex GGT
Bialex Oxalate
Bialex Phosphorus
Bialex Cystine
Bialex Microalbumin
Bialex LDH
Bialex I-Mycobacteria Test
Bialex Ferrozine

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

