



Certificate No. 4359-1-2019

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 device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device 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 January 25, 2019 to January 24, 2021.





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 Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

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





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

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

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2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

Name of Product(s)

ALT/GPT Alanine Aminotransferase
AST/GOT Aspartate Aminotransferase
y-GT/GGT y-Glutamyltransferase
ALP/AKP Alkaline Phosphatase
TBILI Total Bilirubin*
TBILI Total Bilirubin*
DBILI Direct Bilirubin*
DBILI Direct Bilirubin*
TP Total Protein*
ALB Albumin*
CHE Cholinesterase
TBA Total Bile Acid*
UREA Urea*
CREA Creatinine*
UA Uric Acid*
CHOL Cholesterol*
TG Triglycerides*
HDL-C High Density Lipoprotein Cholesterol
LDL-C Low Density Lipoprotein Cholesterol
APOA1 Apolipoprotein A 1*
APOB Apolipoprotein B*
CK Creatine Kinase
CK-MB Creatine Kinase MB Isoenzyme
LOH Lactate Dehydrogenase
a-HBDH a-Hydroxybutyrate Dehydrogenase
a-AMY a-Amylase
LAP Leucine Aminopeptidase
Ca Calcium*
Cl Chloride*
p Inorganic Phosphorus*
Mg Magnesium*
Fe Iron*
GLU Glucose*
GLU Glucose*
FMN Fructosamine*
HBA1C Hemoglobin HBA1C
IgA Immunoglobulin A*
IgA Immunoglobulin A*
IgG Immunoglobulin G*
IgG Immunoglobulin G*
IgM Immunoglobulin M*
IgM Immunoglobulin M*
C3 Complement Component 3*
C3 Complement Component 3*
C4 Complement Component 4*
C4 Complement Component 4*
PA Prealbumin*





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PA Prealbumin*

LA Lactic Acid*

CRP CRP (C-reactive protein)

HBA1C Hemoglobin HBA1C

CAL Multi-Parameter Biochemistry Calibrator

CON Multi-Parameter Biochemistry Control

NCH Highly-effective Detergent (NCH Detergent)

NCH Highly-effective Detergent (NCH Detergent)

PT Prothrombin Time

APTT Activate PartialThromboplastin Time

TT Thrombln Time

FIB Fibrinogen

Standard Solution A

Standard Solution B

Electrode Reconditioning Solution

Electrode Deproteinization Solution

Electrode Electrolytic Solution

Reference Electrode Solution

Diluent (HA-3D)

Deprotein (HA-3D)

Hemolysin (HA-3D)

Detergent (HA-3D)

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

