



Certificate No. 1283-2-2015

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

Name of Manufacturer/Distributor

LABOMED, INC.

2728 S LA CIENEGA BLVD

LOS ANGELES, CA USA 90034

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.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from February 18, 2015 to February 17, 2017.





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Name of Manufacturer/Distributor

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

Name of Product(s)

A524-780TM ALT
A532-200TM A-Amylase
A559-780TM AST
B538-370TM Direct Bilirubin
B549-620TM Total Bilirubin
C501-580TM Chloride
C503-580TM Calcium
C507-940TM Cholesterol
C514-650TM Creatinine
C519-440TM CK
G516-870TM Glucose (hexokinase)
G520-510TM Glucose (Oxidase)
G572-780TM GGT
H513-330TM HDL
I516-780TM Phosphorous
I592-380TM Iron
L530-400TM LDL
L533-780TM LDH
M527-430TM Magnesium
P605-510TM Potassium
P615-780TM TP (CSF/Urine)
T532-1170TM Triglycerides
T528-1300TM Total Protein
U582-1170TM Uric Acid
Alanine Aminotransferase ALT/GPT
Aspartate Aminotransferase AST/GOT
γ-Glutamyltransferase γ-GT/GGT
Alkaline Phosphatase ALP/AKP
Total Bilirubin* TBILI
Total Bilirubin* TBILI
Direct Bilirubin* DBILI
Direct Bilirubin* DBILI
Total Protein* TP
Albumin* ALB
Cholinesterase CHE
Total Bile Acid* TBA
Urea* UREA
Creatinine* CREA
Uric Acid* UA
Cholesterol* CHOL
Triglycerides* TG
High Density Lipoprotein Cholesterol HDL-C
Low Density Lipoprotein Cholesterol LDL-C
Apolipoprotein A 1* APOA1
Apolipoprotein B* APOB
Creatine Kinase CK
Creatine Kinase MB Isoenzyme CK-MB
Lactate Dehydrogenase LOH
α-Hydroxybutyrate Dehydrogenase α-HBDH
α-Amylase α-AMY
Leucine Aminopeptidase LAP
Calcium* Ca





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Chloride* Cl
Inorganic Phosphorus* P
Magnesium* Mg
Iron* Fe
Glucose* GLU
Glucose* GLU
Fructosamine* FMN
Immunoglobulin A* IgA
Immunoglobulin A* IgA
Immunoglobulin G* IgG
Immunoglobulin G* IgG
Immunoglobulin M* IgM
Immunoglobulin M* IgM
Complement Component 3* C3
Complement Component 3* C3
Complement Component 4* C4
Complement Component 4* C4
Prealbumin* PA
Prealbumin* PA
Lactic Acid* LA
Multi-Parameter Biochemistry Calibrator
Multi-Parameter Biochemistry Control
Prothrombin Time PT
Highly-effective Detergent (NCH Detergent)
Prothrombin Time PT
Activate PartialThromboplastin Time APTT
Thrombln Time TT
Fibrinogen FIB
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-----

