



**Certificate No. 7182-3-2021**

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.

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 March 17, 2021 to March 16, 2023.**





U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

**Certificate No. 7182-3-2021**

**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----





**Certificate No. 7182-3-2021**

**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**

LABOMED, INC.  
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\*





**Certificate No. 7182-3-2021**

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

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 Partial Thromboplastin Time  
TT Thrombin 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-----

