



**Certificate No. 7795-3-2021**

**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

(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 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 April 01, 2021 to March 31, 2023.**





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

**Certificate No. 7795-3-2021**

**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. 7795-3-2021**

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

**Name of Product(s)**

Clinical Chemistry Analyzer

BAS-100TS  
BAS-120TS  
BAS-150TS  
CB-200  
DW-20  
EMR-500  
EMW-600  
FACA-200  
FACA-200/ISE  
FACA-261  
FACA-261/ISE  
FACA-301  
FACA-301/ISE  
FACA-401  
FACA-401/ISE  
FACA-601  
FACA-601/ISE  
FACA-801  
FACA-801/ISE  
H-7021  
H-7028  
IO-005  
SCO-2000  
SCO-2002  
SCO-2004  
VH-22

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

