



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 6018-2-2019

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
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See Attached List

See Attached List

(One Page)

(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 March 01, 2019 to February 28, 2021.





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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 1

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Los Angeles, CA USA 90034

Name of Manufacturer

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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-----

