



Certificate No. 2165-11-2016

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

Name of Manufacturer

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 November 23, 2016 to November 22, 2018.





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

Name of Manufacturer

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

Name of Product(s)

FACA-601
FACA-601 ISE
FACA-401
FACA-401 ISE
FACA-301
FACA-301 ISE
FACA-261
FACA-261 ISE
FACA-200
CB-200
BAS-150TS
BAS-120TS
BAS-100TS
EMR-500
EMV-600
H-7021
H-7022
H-7028
IO-005
SCO-2000
VH-22
DW-20

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

