

Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

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

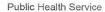
Office of Compliance

Center for Devices and Radiological Health

This certificate is valid from November 23, 2016 to November 22, 2018.









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Certificate No. 2165-11-2016 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

FAC:A-301

FAC;A-301 ISE

FACA-261

FACA-261 ISE

FACA-200

CB-200

BAS-150TS

BAS-120TS

BAS-100TS

EMR-500

EM\V-600

H-7021

H-7022

H-7028 IO-005

SCO-2000

VH-22

DW-20

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

