

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

### Certificate No. 7276-11-2014

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

Name of Manufacturer/Distributor

LABOMED, INC.

2728 S LA CIENEGA BLVD

LOS ANGELES, CA USA 90034

Name of Product(s)

DIAGNOSTIC INSTRUMENTS

FACA 200

FACA 261

FACA 401

FACA 601

FACA 801

H-7021

10-005

SCO-2000

BAS 100TS

**BAS 120TS** 

**BAS 150TS** 

**EMR 500** 

**EMR 600** 

-END OF PRODUCT LIST-

State of California County of

LOS ANGE ES

Subscribed and sworn to (or affirmed)

Before me on this 18 th day of N6V 2014 by

personally known to me or proved to me on the basis of satisfactory evidence to be the person()) who appeared before me.

Signature \_\_\_\_\_\_

(Seal)

A. SHEIKH
Commission # 2005399
Notary Public - California
Los Angeles County
My Comm. Expires Jan 27, 2017





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#### 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/Distributor
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 13, 2014 to November 12, 2016.





