

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

Certificate No. 20595-2-2013

### 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)

Mild Portable Hyperbaric Chamber <4psi Lightweight chamber utilizing atmospheric air

See Attached List (One Page)

### Name of Manufacturer/Distributor, Address

Manufacturer:

Hyperbaric Technologies Incorporated 1 Sam Stratton Road PO Box 69 Amsterdam, NY 12010

<u>Distributor:</u>
Oxy Health LLC
10719 Norwalk Blvd.
Santa Fe Springs, CA 90670

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 product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Ann M. Ferriter

Director

Division of Risk Management Operations

Office of Compliance

Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY STATE OF MARYLAND

Subscribed and sworn to before me this 37 day of Feb month 2013 year.

CATHRYN N MORRIS Notary Public-Maryland Montgomery County My Commission Expires

January 04, 2017



# Certificate to Foreign Government - Attachment (Page 1 of 1 Page)

## Name of Product(s)

## Name of Manufacturer/ Distributor, Address

(Mild Portable Hyperbaric Chamber)		Manufacturer/
15C37175	21" Solace 210	Hyperbaric Technologies Incorporated 1 Sam Stratton Road
15C37176	21" Solace 210 Bladder	
15C37181	27" Respiro 270	PO Box 69
15C37182	27" Respiro 270 Bladder	Amsterdam, NY 12010
15C37178	32" Vitaeris 320	
15C37179	32" Vitaeris 320 Bladder	Distributor. Oxy Health LLC 10719 Norwalk Blvd.
15T38145	32" Quamvis	
15T38141	27" Mild Chamber	
15C38153	32" Chamberlite 320	Santa Fe Springs, CA 90670
15C37199	21" Gamow Mountain Bag	
15C38172	21" Gamow Mountain Bag Ultra-Lite	
15C38154	32" Quamvis Lite	
15C37155	21" Chamberlite 130	*
End of Prod	luct List	

