



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Certificate No. 3297-4-2009

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>
See attached list (1 page)	Manufacturer: SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200

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 products(s) listed above.

Theresa McDonald

Theresa McDonald
Chief, Regulatory Policy and Systems Branch
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 27 day of April month 2009 year.

Cathryn N. Morris

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013



Certificate to Foreign Government – Attachment (Page 1 of 1 Page)

Name of Product(s)

Name of Manufacturer/
Distributor, Address

Tango Non-Invasive BP Monitor (Stress Test)

Tango + Non-Invasive BP Monitor (Stress Test)

Tango + Automatic Blood Pressure and
Oxygen Saturation Measurement System

Accutracker II Non-Invasive BP Monitor (Ambulatory)

Accutracker DX Non-Invasive BP Monitor (Ambulatory)

OSCAR 2 Non-Invasive BP Monitor (Ambulatory)

Pressure Track and Bravo BP Measurement System (Ambulatory)

All Purpose Cuff (Cuff)

Cycle BP Monitor & Pulse Oximeter

247 BP device

“End of Product List”

Manufacturer:
SunTech Medical, Inc..
507 Airport Blvd., Suite 117
Morrisville, NC 27560-8200

