U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 10144-6-2022

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)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Three Pages)	(One Page)

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.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 22, 2022 to June 21, 2024.

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturer
SUNTECH MEDICAL, INC.
5827 S. Miami Boulevard
Suite 100
MORRISVILLE, NC
USA 27560

Contract Manufacturer
SUNTECH MEDICAL DEVICES (SHENZHEN) CO., LTD.
105 Huanguan South Road,Suite15, 2-3/F, Dahe Cummunity
GuanHu Subdistrict, LongHua District,
Shenzhen, Guangdong
CHINA 518110

----END OF MANUFACTURER/DISTRIBUTOR LIST----

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Name of Manufacturer

Manufacturer

SUNTECH MEDICAL, INC.
5827 S. Miami Boulevard
Suite 100
MORRISVILLE, NC
USA 27560

Name of Product(s)

SunTech Tango M2 Blood Pressure Monitor, Model 2130, and Accessories
99-0088-00, Tango M2 without ECG
99-0088-01, Tango M2 with ECG
99-0088-02, Tango M2, Ww, w/o ECG, no Power Cord
99-0088-03, Tango M2, ECG, Ww, no power cord
99-0088-12, Tango M2 Kit, w/ECG
99-0088-14, Tango M2 Standard Kit, Compatabile with GE, RoHS
99-0088-15, Tango M2 Kit, US Standard, Compatabile with Mortara
99-0088-40, Tango M2, w/o ECG
99-0088-41, Tango M2, w/ECG
99-0088-50, Tango M2, Test Report, No ECG, No Power Cord
99-0088-51, Tango M2, Test Report, w/ECG, No Power Cord
99-0132-00, Tango M2 Kit, Compatabile with Marquette CASE/8000
99-0132-01, Tango M2 Kit, Compatabile with Cambridge Heart CH2000
99-0132-04, Tango M2 Kit, Compatabile with Quinton QStress (up to v4.6)/ Q4500
99-0132-05, Tango M2 Kit, Compatabile with Mortara X-Scribe/StressVue/QStress (v6)
99-0132-06, Tango M2 Kit, Compatabile with Midmark Iqmark EZStress
99-0132-07, Tango M2 Kit, Compatabile with Philips ST80i
99-0132-09, Tango M2 Kit, Compatabile with GE CASE
99-0132-10, Tango M2 Kit, Compatabile with GE CASE
99-0132-11, Tango M2 Kit, Compatabile with Welch Allyn CardioPerfect
99-0132-16, Tango M2 Kit, Compatabile with Quinton QStress/Q4500
99-0132-17, Tango M2, Compatabile with Burdick Quest, Pulse Biomedical QRS Card
99-0132-18, TangoM2 kit, Compatabile with Hill-Rom X-Scribe/StressVue
99-0132-19, Tango M2 Kit, Compatabile with Philips ST80i
99-0132-20, Tango M2 Kit, Compatabile with CareFusion Vyntus CPX
99-0027-39, Tango M2 Preventative Maintenance Kit
98-0233-01, LPXpod SpO2 Kit w/Adult Finger Sensor, Tango M2
98-0235-00, Tango M2 microphone, 18"
98-0235-01, Tango M2 Microphone, 12"
98-1009-00, TangoMD ECG Option Upgrade Kit, RoHS
98-1010-00, Tango M2 USB Cable Kit
98-0002-1250, Microphone pads, Bag of 1250
98-0002-250, Microphone pads, Bag of 250
98-0002-50, Microphone pads, Bag of 50
98-0002-500, Microphone pads, Bag of 500
98-0003-00, Wrist Strap, Black
98-0007-50, 50 Cuff Anchor Pads in a bag
98-0030-00, KIT, T-TUBE, NEW CPC-TO-CPC ABP T-Tube
98-0057-00, USB Adapter Cable Kit
91-0003-00, PWR CORD, USA, hospital Grade
91-0003-05, PWR Cord
91-0003-06, PWR Cord
91-0003-07, Power Cord
91-0003-08, Power Cord
91-0003-09, Power cord, RoHS
91-0003-10, Power Cord, RoHS
91-0003-11, Power cord, RoHS
91-0003-12, Power cord, RoHS

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91-0003-17, Power cord, RoHS
91-0003-18, Power cord, RoHS
91-0003-19, Power cord, RoHS
91-0003-26, Power cord, RoHS
91-0004-00, Patient leads, ECG cable
91-0009-01, BNC to RS232 ECG trigger cable, RoHS
91-0010-01, 8 Pin Mini-Din To RS232 Cable, RoHS
91-0011-01, BNC ECG trigger cable, RoHS
91-0013-01, RS232 Communication cable, RoHS
91-0018-02, BNC to Mono Phono ECG trigger cable, RoHS
91-0018-03, BNC to Stereo ECG trigger cable, RoHS
91-0022-00, Cable, Compatabile with Schiller, Digital ECG, RoHS
91-0035-00, Cable, RS232, Compatabile with Schiller, RoHS
91-0053-01, ECG Splitter cable, RoHS
91-0061-01, RS232 Interface Cable, RoHS, compatible with Nihon Koden
91-0065-01, Tango M2 To CH2000 RS232 Interface Cable, RoHS
91-0066-01, Tango to Stress System DB25 ECG Interface Cable, RoHS
91-0069-00, 8 pin mini din Splitter Cable
91-0076-00, Cable, extension for headphone
91-0125-01, Cable, SpO2, LPXpod, 2m
91-0127-01, Tango M2 Hose, RoHS
91-0127-03, Tango M2 Hose, RoHS, Dual Female Bayonet
91-0127-04, Tango M2 Hose, RoHS, QC and Female Bayonet
52-0003-00, Finger Clip Sensor, SPO2, Purelight, Adult, 1 meter
51-0002-00, Headphones Mini w/vol adjust.
51-0000-00, Headphone w/o extension cable
46-0040-02, Tango M2 Mount, for Mobile Stand, Deluxe
46-0040-00, Mobile Stand, Deluxe
36-0001-01, Clamp, Pole, Encapsulated Screws
19-0012-01, Power Supply, 9V @ 5A 120/240V, Isolated Ground

Name of Manufacturer
Contract Manufacturer

SUNTECH MEDICAL DEVICES (SHENZHEN) CO., LTD.
105 Huanguan South Road,Suite15, 2-3/F, Dahe Cummunity
GuanHu Subdistrict, LongHua District,
Shenzhen, Guangdong
CHINA 518110

Name of Product(s)

98-0061-01, Orbit K Cuff W/O Mic Small Adult
98-0061-02, Orbit K Cuff W/O Mic Adult
98-0061-03, Orbit K Cuff W/O Mic Large Adult
98-0061-05, Orbit K Cuff W/O Mic Adult Plus
98-0061-24, Small Adult Orbit-K Cuff, Bayonet
98-0061-25, Adult Orbit-K Cuff, Bayonet
98-0061-26, Large Adult Orbit-K Cuff, Bayonet
98-0061-27, Adult Plus Orbit-K Cuff, Bayonet
98-0062-21, Orbit K Cuff, w/Mic2, Small Adult
98-0062-22, Orbit K Cuff, w/Mic2 - Adult
98-0062-23, Orbit K Cuff w/Mic2. - Large Adult
98-0062-25, Orbit K Cuff w/Mic2,- Adult Plus
98-0062-34, Small Adult Orbit-K Cuff with Microphone, Bayonet
98-0062-35, Adult Orbit-K Cuff with Microphone, Bayonet
98-0062-36, Large Adult Orbit-K Cuff with Microphone, Bayonet
98-0062-37, Adult Plus Orbit-K Cuff with Microphone, Bayonet
98-0700-01, Single Use Kit Small Adult (Disposable Cuff and Mic pad)
98-0700-02, Single Use Kit Adult (Disposable Cuff and Mic pad)

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98-0700-03, Single Use Kit Adult Long (Disposable Cuff and Mic pad)
98-0700-04, Single Use Kit Large Adult (Disposable Cuff and Mic pad)
98-0700-05, Single Use Kit Large Adult Long (Disposable Cuff and Mic pad)
————————END OF PRODUCT LIST————————