



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

**Certificate No. 10212-6-2022**

**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)**

See Attached List

(Two Pages)

**Name of Manufacturer/Distributor, Address**

See Attached List

(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 24, 2022 to June 23, 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, Suite 15, 2-3/F, Dahe Community  
GuanHu Subdistrict, LongHua District,  
Shenzhen, Guangdong  
CHINA 518110

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







**Certificate No. 10212-6-2022**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2**

**Name of Manufacturer**

**Manufacturer**

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

**Name of Product(s)**

SunTech CT40 Spot-check Vital Signs Devices  
99-0134-03, System, CT40 Model 260, w/Power Cord  
99-0134-02, System, CT40 Model 260, w/Power Cord  
99-0134-01, System, CT40 Model 260, w/Power Cord  
99-0134-00, System, CT40, Model 260, Standard, no power cord  
98-0412-00, Replacement IR Thermometer with cable  
98-0411-03, Temp Kit, IR, CT40, M260  
98-0411-02, Temp Kit, Filac 3000, CT40, M260  
98-0411-01, SpO2 Kit, Masimo, CT40, M260  
98-0411-00, SpO2 Kit, ChipOx, CT40, M260  
91-0100-02, Cable, 6ft USB 2.0 A Male to Mini-B 5pin Male 28/24AWG with Ferrite Core  
71-0543-00, Paper Roll, Thermal Printer, 80mm WD x 12MM LG x 33MM OD. Pack of 10  
52-0011-00, CT40 Filac 3000 Calibration Verification Plug  
52-0010-00, SpO2 sensor, Adult Reusable, Nellcor compatible  
46-0040-01, Thermal Printer Mount, for Mobile Stand, Deluxe  
45-0006-01, F3000 Rectal Isolation Chamber, Red  
45-0006-00, F3000 Oral/Axillary Isolation Chamber, Blue  
45-0005-00, Dongle, Wi-Fi, D-Link DWA-171  
52-0009-00, Temp Probe, Oral, 9 ft, Filac  
52-0009-01, Temp Probe, Rectal, 9 ft, Filac  
98-0130-00, F3000 Disposable Temp Probe Covers (Qty 5000)  
98-0130-01, F3000 Disposable Temp Probe Covers (Qty 5000)  
98-0131-00, F3000 Disposable Temp Probe Covers (Qty 500)  
98-0131-01, Disposable Probe Covers, 500  
98-0257-03, Barcode Scanner, 1D  
98-0257-04, Barcode Scanner, 2D  
98-0811-00, Wall Bracket Kit, CT40  
46-0040-00, Deluxe Mobile Stand  
98-0256-00, CT40 Thermal Printer (w/USB, paper)  
91-0028-16, Straight Black Hose, Female Bayonet to Female Bayonet, 10ft (3m)  
17-0022-00, Battery, Li-ion, 7.2V 6.6 Ah  
91-0003-00, AC Power Cord  
91-0003-05, AC Power Cord  
91-0003-06, AC Power Cord  
98-0900-00, Replacement Battery, 18650 Li-ion pack, 7.26V 6.6 Ah

**Name of Manufacturer**

**Contract Manufacturer**

SUNTECH MEDICAL DEVICES (SHENZHEN) CO., LTD.  
105 Huanguan South Road, Suite 15, 2-3/F, Dahe Community  
GuanHu Subdistrict, LongHua District,  
Shenzhen, Guangdong  
CHINA 518110

**Name of Product(s)**

98-0600-4K, Cuff, SunTech Dur OPD, Small Adult Plus, 1-Tube, Bayonet, Box of 5  
98-0600-4C, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Bayonet, Box of 5  
98-0600-4A, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Bayonet, Box of 5  
98-0600-49, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Bayonet, Box of 5







**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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98-0600-47, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Bayonet, Box of 5

98-0600-45, Cuff, SunTech Dur OPD, Adult, 1-Tube, Bayonet, Box of 5

98-0600-43, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Bayonet, Box of 5

98-0600-41, Cuff, SunTech Dur OPD, Child, 1-Tube, Bayonet, Box of 5

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

