



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

Certificate No. 10325-6-2022

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

(Four 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

Legal 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----





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Name of Manufacturer

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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

Name of Product(s)

SunTech Eclipse Non-invasive Blood Pressure Cuff, Model SELF100

98-0068-06, Cuff, D-Ring, Pediatric, Eclipse, 4' Hose with Female Metal Bayonet Connector

98-0068-07, Cuff, D-Ring, Small Adult, Eclipse, 4' Hose with Female Metal Bayonet Connector

98-0068-08, Cuff, D-Ring, Adult, Eclipse, 4' Hose with Female Metal Bayonet Connector

98-0068-09, Cuff, D-Ring, Large Adult, Eclipse, 4' Hose with Female Metal Bayonet Connector

98-0068-11, Cuff, D-Ring, Pediatric Eclipse

98-0068-12, Cuff, D-Ring, Small Adult, Eclipse

98-0068-13, Cuff, D-Ring, Adult, Eclipse

98-0068-14, Cuff, D-Ring, Large Adult, Eclipse

SunTech Durable Non-invasive Blood Pressure Cuff

98-0080-01, Cuff, All Purpose, General, Infant

98-0080-02, Cuff, All Purpose, General, Child

98-0080-03, Cuff, All Purpose, General, Child Long

98-0080-04, Cuff, All Purpose, General, Small Adult

98-0080-05, Cuff, All Purpose, General, Small Adult Long

98-0080-06, Cuff, All Purpose, General, Adult

98-0080-07, Cuff, All Purpose, General, Adult Long

98-0080-08, Cuff, All Purpose, General, Large Adult

98-0080-09, Cuff, All Purpose, General, Large Adult Long

98-0080-10, Cuff, All-Purpose, General, Thigh

98-0080-31, APC, Infant, Slip Luer Female

98-0080-32, Cuff, All Purpose, Child, Slip Luer Female, Plastic

98-0080-34, Cuff, All Purpose, Small Adult, Slip Luer Female, Plastic

98-0080-35, APC, SA long, Slip Lr, female

98-0080-36, APC, Adult, Slip Lr, female

98-0080-37, APC, Adult lg, Slip Lr, female

98-0080-38, APC, Lge Adult, Slip Lr, female

98-0080-39, APC, Lge Adult lg, Slip, Fem

98-0080-40, APC, Thigh, Slip Luer, Female

98-0082-01, Cuff, All Purpose, General, Infant, Dual Lumen

98-0082-02, Cuff, All Purpose, General, Child, Dual Lumen

98-0082-03, Cuff, All Purpose, General, Child LONG, Dual Lumen

98-0082-04, Cuff, All Purpose, General, Small Adult, Dual Lumen

98-0082-05, Cuff, All Purpose, General, Small Adult LONG, Dual Lumen

98-0082-06, Cuff, All Purpose, General, Adult, Dual Lumen

98-0082-07, Cuff, All Purpose, General, Adult LONG, Dual Lumen

98-0082-08, Cuff, All Purpose, General, Large Adult, Dual Lumen

98-0082-09, Cuff, All Purpose, General, Large Adult LONG, Dual Lumen

98-0082-10, Cuff, All Purpose, General, Thigh, Dual Lumen

98-0084-21, Cuff, All Purpose, Infant, SunTech, Threaded

98-0084-22, Cuff, All Purpose, Child, SunTech, Threaded

98-0084-24, Cuff, All Purpose, Small Adult, SunTech, Threaded





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98-0084-25, Cuff, All Purpose, Small Adult LONG, SunTech, Threaded
98-0084-26, Cuff, All Purpose, Adult, SunTech, Threaded
98-0084-27, Cuff, All Purpose, Adult LONG, SunTech, Threaded
98-0084-28, Cuff, All Purpose, Large Adult, SunTech, Threaded
98-0084-29, Cuff, All Purpose, Large Adult LONG, SunTech, Threaded
98-0084-30, Cuff, All Purpose, Thigh, SunTech, Threaded
98-0084-31, Cuff, All Purpose, Infant, Quick Conn Male
98-0084-32, Cuff, All Purpose, Child, Quick Conn Male
98-0084-33, APC ChildLONG QuickConnectMale
98-0084-34, Cuff, All Purpose, Small Adult, Quick Conn Male
98-0084-35, APC SmAdultLONG QuickConnMale
98-0084-36, Cuff, All Purpose, Adult, Quick Conn Male
98-0084-37, Cuff, All Purpose, Adult LONG, Quick Conn Male
98-0084-38, Cuff, All Purpose, Large Adult, Quick Conn Male
98-0084-39, Cuff, All Purpose, Large Adult LONG, Quick Conn Male
98-0084-40, Cuff, All Purpose, Thigh, Quick Conn Male
98-0084-41, Cuff, All Purpose, Infant, Rectus
98-0084-42, Cuff, All Purpose, Child, Rectus
98-0084-44, Cuff, All Purpose, Small Adult, Rectus
98-0084-45, Cuff, All Purpose, Small Adult LONG, Rectus
98-0084-46, Cuff, All Purpose, Adult, Rectus
98-0084-47, Cuff, All Purpose, Adult LONG, Rectus
98-0084-48, Cuff, All Purpose, Large Adult, Rectus
98-0084-49, Cuff, All Purpose, Large Adult LONG, Rectus
98-0084-50, Cuff, All Purpose, Thigh, Rectus
98-0084-71, Cuff, All Purpose, Infant, Rectus, Bayonet, Plastic
98-0084-72, Cuff, All Purpose, Child, Rectus, Bayonet, Plastic
98-0084-73, Cuff, All Purpose, Child LONG, Rectus, Bayonet, Plastic
98-0084-74, Cuff, All Purpose, Small Adult, Rectus, Bayonet, Plastic
98-0084-75, Cuff, All Purpose, Small Adult LONG, Rectus, Bayonet, Plastic
98-0084-76, Cuff, All Purpose, Adult, Rectus, Bayonet, Plastic
98-0084-77, Cuff, All Purpose, Adult LONG, Rectus, Bayonet
98-0084-78, Cuff, All Purpose, Large Adult, Rectus, Bayonet
98-0084-79, Cuff, All Purpose, Large Adult LONG, Rectus, Bayonet
98-0084-80, Cuff, All Purpose, Thigh, Rectus, Bayonet
98-0085-22, Cuff, All Purpose, Child, 2-Tube, SunTech, Threaded
98-0085-24, Cuff, All Purpose, Small Adult, 2-Tube, SunTech, Threaded
98-0085-25, Cuff, All Purpose, Small Adult Long, 2-Tube, SunTech, Threaded
98-0085-26, Cuff, All Purpose, Adult, 2-Tube, SunTech, Threaded
98-0085-27, Cuff, All Purpose, Adult LONG, 2-Tube, SunTech, Threaded
98-0085-28, Cuff, All Purpose, Large Adult, 2-Tube, SunTech, Threaded
98-0085-29, Cuff, All Purpose, Large Adult Long, 2-Tube, SunTech, Threaded
98-0085-30, Cuff, All Purpose, Thigh, 2-Tube, SunTech, Threaded
98-0085-34, Cuff, All Purpose, Small Adult, 2-Tube, Quick Conn Male
98-0085-36, Cuff, All Purpose, Adult, 2-Tube, Quick Conn Male
98-0085-37, Cuff, All Purpose, Adult LONG, 2-Tube, Quick Conn Male
98-0085-38, Cuff, All Purpose, Large Adult, 2-Tube, Quick Conn Male
98-0085-39, Cuff, All Purpose, Large Adult Long, 2-Tube, Quick Conn Male
98-0085-40, Cuff, All Purpose, Thigh, 2-Tube, Quick Conn Male
98-0085-44, Cuff, All Purpose, Small Adult, 2-Tube, Rectus
98-0085-46, Cuff, All Purpose, Adult, 2-Tube, Rectus
98-0085-47, Cuff, All Purpose, Adult LONG, 2-Tube, Rectus
98-0085-48, Cuff, All Purpose, Large Adult, 2-Tube, Rectus
98-0085-49, Cuff, All Purpose, Large Adult Long, 2-Tube, Rectus
98-0085-50, Cuff, All Purpose, Thigh, 2-Tube, Rectus
98-0085-62, APC Child 2Tube QuickConnectMF
98-0085-64, Cuff, All Purpose, Small Adult, 2-Tube, QuickConn Male/Fem
98-0085-65, APC SmAdltLONG 2Tub QuickConMF





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98-0085-66, Cuff, All Purpose, Adult, 2-Tube, QuickConn Male/Fem
98-0085-67, Cuff, All Purpose, Adult LONG, 2-Tube, QuickConn Male/Fem
98-0085-68, Cuff, All Purpose, Large Adult, 2-Tube, QuickConn Male/Fem
98-0085-69, Cuff, All Purpose, Large Adult LONG, 2-Tube, QuickConn Male/Fem
98-0085-70, Cuff, All Purpose, Thigh, 2-Tube, QuickConn Male/Fem
98-0085-74, Cuff, All Purpose, Small Adult, 2-Tube, Male Bayonet, Plastic
98-0085-76, Cuff, All Purpose, Adult, 2-Tube, Male Bayonet, Plastic
98-0085-77, Cuff, All Purpose, Adult LONG, 2-Tube, Male Bayonet, Plastic
98-0085-78, Cuff, All Purpose, Large Adult, 2-Tube, Male Bayonet, Plastic
98-0085-79, Cuff, All Purpose, Large Adult LONG, 2-Tube, Male Bayonet, Plastic
98-0085-80, Cuff, All Purpose, Thigh, 2-Tube, Male Bayonet, Plastic
98-0600-00, Cuff, SunTech Dur OPD, Infant, 1-Tube, Fem Quick Conn, Box of 5
98-0600-01, Cuff, SunTech Dur OPD, Child, 1-Tube, Fem Quick Conn, Box of 5
98-0600-03, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Fem Quick Conn, Box of 5
98-0600-05, Cuff, SunTech Dur OPD, Adult, 1-Tube, Fem Quick Conn, Box of 5
98-0600-06, Cuff, SunTech Dur OPD, Adult Long, 1-Tube, Fem Quick Conn, Box of 5
98-0600-07, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Fem Quick Conn, Box of 5
98-0600-08, Cuff, SunTech Durable One-Piece Cuff, Large Adult Long, 1-Tube, Female Quick Connect, Box of 5
98-0600-09, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Fem Quick Conn, Box of 5
98-0600-0A, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Fem Quick Conn, Box of 5
98-0600-0C, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Fem Quick Conn, Box of 5
98-0600-0K, SunTech Dur OPD, Small Adult Plus, 1-Tube, Fem Quick Conn, Box of 5
98-0600-10, Cuff, SunTech Dur OPD, Infant, 2-Tube, Fem Quick Conn, Box of 5
98-0600-11, Cuff, SunTech Dur OPD, Child, 2-Tube, Fem Quick Conn, Box of 5
98-0600-13, Cuff, SunTech Dur OPD, Small Adult, 2-Tube, Fem Quick Conn, Box of 5
98-0600-15, Cuff, SunTech Dur OPD, Adult, 2-Tube, Fem Quick Conn, Box of 5
98-0600-16, Cuff, SunTech Durable One-Piece Cuff, Adult Long, 2-Tube, Female Quick Connect, Box of 5
98-0600-17, Cuff, SunTech Dur OPD, Large Adult, 2-Tube, Fem Quick Conn, Box of 5
98-0600-18, Cuff, SunTech Durable One-Piece Cuff, Large Adult Long, 2-Tube, Female Quick Connect, Box of 5
98-0600-19, Cuff, SunTech Dur OPD, Thigh, 2-Tube, Fem Quick Conn, Box of 5
98-0600-1A, Cuff, SunTech Dur OPD, Adult Plus, 2-Tube, Fem Quick Conn, Box of 5
98-0600-1C, Cuff, SunTech Dur OPD, Large Adult Plus, 2-Tube, Fem Quick Conn, Box of 5
98-0600-1K, Cuff, SunTech Dur OPD, Small Adult Plus, 2-Tube, Fem Quick Conn, Box of 5
98-0600-20, Cuff, SunTech Dur OPD, Infant, 1-Tube, Screw Conn, Box of 5
98-0600-21, Cuff, SunTech Dur OPD, Child, 1-Tube, Screw Conn, Box of 5
98-0600-23, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Screw Conn, Box of 5
98-0600-25, Cuff, SunTech Dur OPD, Adult, 1-Tube, Screw Conn, Box of 5
98-0600-26, Cuff, SunTech Dur OPD, Adult Long, 1-Tube, Screw Conn, Box of 5
98-0600-27, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Screw Conn, Box of 5
98-0600-28, Cuff, SunTech Dur OPD, Large Adult Long, 1-Tube, Screw Conn, Box of 5
98-0600-29, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Screw Conn, Box of 5
98-0600-2A, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Screw Conn, Box of 5
98-0600-2C, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Screw Conn, Box of 5
98-0600-2K, Cuff, SunTech Dur OPD, Small Adult Plus, 1-Tube, Screw Conn, Box of 5
98-0600-30, Cuff, SunTech Dur OPD, Infant, 2-Tube, Screw Conn, Box of 5
98-0600-31, Cuff, SunTech Dur OPD, Child, 2-Tube, Screw Conn, Box of 5
98-0600-33, Cuff, SunTech Dur OPD, Small Adult, 2-Tube, Screw Conn, Box of 5
98-0600-35, Cuff, SunTech Dur OPD, Adult, 2-Tube, Screw Conn, Box of 5
98-0600-36, Cuff, SunTech Dur OPD, Adult Long, 2-Tube, Screw Conn, Box of 5
98-0600-37, Cuff, SunTech Dur OPD, Large Adult, 2-Tube, Screw Conn, Box of 5
98-0600-38, Cuff, SunTech Dur OPD, Large Adult Long, 2-Tube, Screw Conn, Box of 5
98-0600-39, Cuff, SunTech Dur OPD, Thigh, 2-Tube, Screw Conn, Box of 5
98-0600-3A, Cuff, SunTech Dur OPD, Adult Plus, 2-Tube, Screw Conn, Box of 5
98-0600-3C, Cuff, SunTech Dur OPD, Large Adult Plus, 2-Tube, Screw Conn, Box of 5
98-0600-3K, Cuff, SunTech Dur OPD, Small Adult Plus, 2-Tube, Screw Conn, Box of 5
98-0600-40, Cuff, SunTech Dur OPD, Infant, 1-Tube, Bayonet, Box of 5
98-0600-41, Cuff, SunTech Dur OPD, Child, 1-Tube, Bayonet, Box of 5
98-0600-43, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Bayonet, Box of 5





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98-0600-45, Cuff, SunTech Dur OPD, Adult, 1-Tube, Bayonet, Box of 5
98-0600-46, Cuff, SunTech Dur OPD, Adult Long, 1-Tube, Bayonet, Box of 5
98-0600-47, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Bayonet, Box of 5
98-0600-48, Cuff, SunTech Dur OPD, Large Adult Long, 1-Tube, Bayonet, Box of 5
98-0600-49, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Bayonet, Box of 5
98-0600-4A, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Bayonet, Box of 5
98-0600-4C, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Bayonet, Box of 5
98-0600-4K, Cuff, SunTech Dur OPD, Small Adult Plus, 1-Tube, Bayonet, Box of 5
98-0600-D0, Cuff, SunTech Dur OPD, Infant, 1-Tube, Male Quick Conn, Box of 5
98-0600-D1, Cuff, SunTech Dur OPD, Child, 1-Tube, Male Quick Conn, Box of 5
98-0600-D3, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Male Quick Conn, Box of 5
98-0600-D5, Cuff, SunTech Dur OPD, Adult, 1-Tube, Male Quick Conn, Box of 5
98-0600-D6, Cuff, SunTech Dur OPD, Adult Long, 1-Tube, Male Quick Conn, Box of 5
98-0600-D7, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Male Quick Conn, Box of 5
98-0600-D8, Cuff, SunTech Dur OPD, Large Adult Long, 1-Tube, Male Quick Conn, Box of 5
98-0600-D9, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Male Quick Conn, Box of 5
98-0600-DA, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Male Quick Conn, Box of 5
98-0600-DC, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Male Quick Conn, Box of 5
98-0600-DK, Cuff, SunTech Dur OPD, Small Adult Plus, 1-Tube, Male Quick Conn, Box of 5
98-0600-E0, Cuff, SunTech Dur OPD, Infant, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E1, Cuff, SunTech Dur OPD, Child, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E3, Cuff, SunTech Dur OPD, Small Adult, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E5, Cuff, SunTech Dur OPD, Adult, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E6, Cuff, SunTech Dur OPD, Adult Long, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E7, Cuff, SunTech Dur OPD, Large Adult, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E8, Cuff, SunTech Dur OPD, Large Adult Long, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-E9, Cuff, SunTech Dur OPD, Thigh, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-EA, Cuff, SunTech Dur OPD, Adult Plus, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-EC, Cuff, SunTech Dur OPD, Large Adult Plus, 1-Tube, Male Metal Bayonet, Box of 5
98-0600-EK, Cuff, SunTech Dur OPD, Small Adult Plus, 1T, Male Bayo, Box of 5
98-0600-F0, Cuff, SunTech Dur OPD, Infant, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F1, Cuff, SunTech Dur OPD, Child, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F3, Cuff, SunTech Dur OPD, Small Adult, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F5, Cuff, SunTech Dur OPD, Adult, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F6, Cuff, SunTech Dur OPD, Adult Long, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F7, Cuff, SunTech Dur OPD, Large Adult, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F8, Cuff, SunTech Dur OPD, Large Adult Long, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-F9, Cuff, SunTech Dur OPD, Thigh, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-FA, Cuff, SunTech Dur OPD, Adult Plus, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-FC, Cuff, SunTech Dur OPD, Lrg Adult Plus, 2-Tube, Male and Fem Quick Conn, Box of 5
98-0600-80, Cuff, SunTech Durable One-Piece Cuff, Infant, 1-Tube, Sphygmomanometer
98-0600-81, Cuff, SunTech Durable One-Piece Cuff, Child, 1-Tube, Sphygmomanometer
98-0600-83, Cuff, SunTech Durable One-Piece Cuff, Small Adult, 1-Tube, Sphygmomanometer
98-0600-85, Cuff, SunTech Durable One-Piece Cuff, Adult, 1-Tube, Sphygmomanometer
98-0600-86, Cuff, SunTech Durable One-Piece Cuff, Adult Long, 1-Tube, Sphygmomanometer
98-0600-87, Cuff, SunTech Durable One-Piece Cuff, Large Adult, 1-Tube, Sphygmomanometer
98-0600-88, Cuff, SunTech Durable One-Piece Cuff, Large Adult Long, 1-Tube, Sphygmomanometer
98-0600-89, Cuff, SunTech Durable One-Piece Cuff, Thigh, 1-Tube, Sphygmomanometer

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

