



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

**Certificate No. 10330-6-2022**

**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

(Three 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 27, 2022 to June 26, 2024.**







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**Certificate No. 10330-6-2022**

**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---







**Certificate No. 10330-6-2022**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3**

**Name of Manufacturer**

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SUNTECH MEDICAL, INC.

5827 S. Miami Boulevard

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MORRISVILLE, NC

USA 27560

**Contract Manufacturer**

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105 Huanguan South Road, Suite 15, 2-3/F, Dahe Community

GuanHu Subdistrict, LongHua District,

Shenzhen, Guangdong

CHINA 518110

**Name of Product(s)**

98-0400-00, Cuff, Disposable, Infant, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-01, Cuff, Disposable, Child, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-03, Cuff, Disposable, Small Adult, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-05, Cuff, Disposable, Adult, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-07, Cuff, Disposable, Large Adult, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-09, Cuff, Disposable, Thigh, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-0A, Cuff, Disposable, Adult Plus, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-0C, Cuff, Disposable, Large Adult Plus, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-0K, Cuff, Disposable, Small Adult Plus, 1-Tube, Fem Quick Connector, Box of 20  
98-0400-10, Cuff, Disposable, Infant, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-11, Cuff, Disposable, Child, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-13, Cuff, Disposable, Small Adult, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-15, Cuff, Disposable, Adult, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-17, Cuff, Disposable, Large Adult, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-19, Cuff, Disposable, Thigh, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-1A, Cuff, Disposable, Adult Plus, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-1C, Cuff, Disposable, Large Adult Plus, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-1K, Cuff, Disposable, Small Adult Plus, 2-Tube, Fem Quick Connector, Box of 20  
98-0400-20, Cuff, Disposable, Infant, 1-Tube, Screw Connector, Box of 20  
98-0400-21, Cuff, Disposable, Child, 1-Tube, Screw Connector, Box of 20  
98-0400-23, Cuff, Disposable, Small Adult, 1-Tube, Screw Connector, Box of 20  
98-0400-25, Cuff, Disposable, Adult, 1-Tube, Screw Connector, Box of 20  
98-0400-27, Cuff, Disposable, Large Adult, 1-Tube, Screw Connector, Box of 20  
98-0400-29, Cuff, Disposable, Thigh, 1-Tube, Screw Connector, Box of 20  
98-0400-2A, Cuff, Disposable, Adult Plus, 1-Tube, Screw Connector, Box of 20  
98-0400-2C, Cuff, Disposable, Large Adult Plus, 1-Tube, Screw Connector, Box of 20  
98-0400-2K, Cuff, Disposable, Small Adult Plus, 1-Tube, Screw Connector, Box of 20  
98-0400-30, Cuff, Disposable, Infant, 2-Tube, Screw Connector, Box of 20  
98-0400-31, Cuff, Disposable, Child, 2-Tube, Screw Connector, Box of 20  
98-0400-33, Cuff, Disposable, Small Adult, 2-Tube, Screw Connector, Box of 20  
98-0400-35, Cuff, Disposable, Adult, 2-Tube, Screw Connector, Box of 20  
98-0400-37, Cuff, Disposable, Large Adult, 2-Tube, Screw Connector, Box of 20  
98-0400-39, Cuff, Disposable, Thigh, 2-Tube, Screw Connector, Box of 20  
98-0400-3A, Cuff, Disposable, Adult Plus, 2-Tube, Screw Connector, Box of 20  
98-0400-3C, Cuff, Disposable, Large Adult Plus, 2-Tube, Screw Connector, Box of 20  
98-0400-3K, Cuff, Disposable, Small Adult Plus, 2-Tube, Screw Connector, Box of 20  
98-0400-40, Cuff, Disposable, Infant, 1-Tube, Bayonet, Box of 20  
98-0400-41, Cuff, Disposable, Child, 1-Tube, Bayonet, Box of 20  
98-0400-43, Cuff, Disposable, Small Adult, 1-Tube, Bayonet, Box of 20  
98-0400-45, Cuff, Disposable, Adult, 1-Tube, Bayonet, Box of 20  
98-0400-47, Cuff, Disposable, Large Adult, 1-Tube, Bayonet, Box of 20  
98-0400-49, Cuff, Disposable, Thigh, 1-Tube, Bayonet, Box of 20







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98-0400-4A, Cuff, Disposable, Adult Plus, 1-Tube, Bayonet, Box of 20  
98-0400-4C, Cuff, Disposable, Large Adult Plus, 1-Tube, Bayonet Box of 20  
98-0400-4K, Cuff, Disposable, Small Adult Plus, 1-Tube, Bayonet Box of 20  
98-0400-50, Cuff, Disp, Infant, 2-Tube, Bayonet, Box of 20  
98-0400-51, Cuff, Disp, Child, 2-Tube, Bayonet, Box of 20  
98-0400-53, Cuff, Disp, Small Adult, 2-Tube, Bayonet, Box of 20  
98-0400-55, Cuff, Disp, Adult, 2-Tube, Bayonet, Box of 20  
98-0400-57, Cuff, Disp, Large Adult, 2-Tube, Bayonet, Box of 20  
98-0400-59, Cuff, Disp, Thigh, 2-Tube, Bayonet, Box of 20  
98-0400-5A, Cuff, Disp, Adult Plus, 2-Tube, Bayonet, Box of 20  
98-0400-5C, Cuff, Disp, Large Adult Plus, 2-Tube, Bayonet, Box of 20  
98-0400-5K, Cuff, Disp, Small Adult Plus, 2-Tube, Bayonet, Box of 20  
98-0400-60, Cuff, Disp, Infant, 1-Tube, No Connector, Box of 20  
98-0400-61, Cuff, Disp, Child, 1-Tube, No Connector, Box of 20  
98-0400-63, Cuff, Disp, Small Adult, 1-Tube, No Connector, Box of 20  
98-0400-65, Cuff, Disp, Adult, 1-Tube, No Connector, Box of 20  
98-0400-67, Cuff, Disp, Large Adult, 1-Tube, No Connector, Box of 20  
98-0400-69, Cuff, Disp, Thigh, 1-Tube, No Connector, Box of 20  
98-0400-6A, Cuff, Disp, Adult Plus, 1-Tube, No Connector, Box of 20  
98-0400-6C, Cuff, Disp, Large Adult Plus, 1-Tube, No Connector, Box of 20  
98-0400-6K, Cuff, Disp, Small Adult Plus, 1-Tube, No Connector, Box of 20  
98-0400-70, Cuff, Disp, Infant, 2-Tube, No Connector, Box of 20  
98-0400-71, Cuff, Disp, Child, 2-Tube, No Connector, Box of 20  
98-0400-73, Cuff, Disp, Small Adult, 2-Tube, No Connector, Box of 20  
98-0400-75, Cuff, Disp, Adult, 2-Tube, No Connector, Box of 20  
98-0400-77, Cuff, Disp, Large Adult, 2-Tube, No Connector, Box of 20  
98-0400-79, Cuff, Disp, Thigh, 2-Tube, No Connector, Box of 20  
98-0400-7A, Cuff, Disp, Adult Plus, 2-Tube, No Connector, Box of 20  
98-0400-7C, Cuff, Disp, Large Adult Plus, 2-Tube, No Connector, Box of 20  
98-0400-7K, Cuff, Disposable, Small Adult Plus, 2-Tube, Box of 20  
98-0400-80, Cuff, Disp, Neonate #1, 1-Tube, Male Slip Luer, Box of 20  
98-0400-81, Cuff, Disp, Neonate #2, 1-Tube, Male Slip Luer, Box of 20  
98-0400-82, Cuff, Disp, Neonate #3, 1-Tube, Male Slip Luer, Box of 20  
98-0400-83, Cuff, Disp, Neonate #4, 1-Tube, Male Slip Luer, Box of 20  
98-0400-84, Cuff, Disp, Neonate #5, 1-Tube, Male Slip Luer, Box of 20  
98-0400-85, Cuff, Disp, Neonate #1, 2-Tube, Male Slip Luer, Box of 20  
98-0400-86, Cuff, Disp, Neonate #2, 2-Tube, Male Slip Luer, Box of 20  
98-0400-87, Cuff, Disp, Neonate #3, 2-Tube, Male Slip Luer, Box of 20  
98-0400-88, Cuff, Disp, Neonate #4, 2-Tube, Male Slip Luer, Box of 20  
98-0400-89, Cuff, Disp, Neonate #5, 2-Tube, Male Slip Luer, Box of 20  
98-0400-90, Cuff, Disp, Neonate #5, 1-Tube, Male Bayonet, Box of 20  
98-0400-91, Cuff, Disp, Neonate #5, 2-Tube, Male Bayonet, Box of 20  
98-0400-92, Cuff, Disp, Neonate #4, 2-Tube, Male Bayonet, Box of 20  
98-0400-93, Cuff, Disp, Neonate #3, 2-Tube, Male Bayonet, Box of 20  
98-0400-94, Cuff, Disp, Neonate #2, 2-Tube, Male Bayonet, Box of 20  
98-0400-95, Cuff, Disp, Neonate #1, 2-Tube, Male Bayonet, Box of 20  
98-0400-96, Cuff, Disp, Neonate #2, 1-Tube, Male Bayonet, Box of 20  
98-0400-97, Cuff, Disp, Neonate #3, 1-Tube, Male Bayonet, Box of 20  
98-0400-98, Cuff, Disp, Neonate #4, 1-Tube, Male Bayonet, Box of 20  
98-0400-99, Cuff, Disp, Neonate #1, 1-Tube, Male Bayonet, Box of 20  
98-0401-01, Cuff, Disposable, Large Adult Plus  
98-0401-06, Cuff, Disposable, Infant, 1-Tube  
98-0401-07, Cuff, Disposable, Infant, 2-Tube  
98-0402-01, Cuff, Disposable, Child  
98-0402-06, Cuff, Disposable, Child, 1-Tube  
98-0402-07, Cuff, Disposable, Child, 2-Tube  
98-0404-01, Cuff, Disposable, Small Adult  
98-0404-06, Cuff, Disposable, Small Adult, 1-Tube







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98-0404-07, Cuff, Disposable, Small Adult, 2-Tube  
98-0406-01, Cuff, Disposable, Adult  
98-0406-06, Cuff, Disposable, Adult, 1-Tube  
98-0406-07, Cuff, Disposable, Adult, 2-Tube  
98-0408-01, Cuff, Disposable, Large Adult  
98-0408-06, Cuff, Disposable, Large Adult, 1-Tube  
98-0408-07, Cuff, Disposable, Large Adult, 2-Tube  
98-040A-01, Cuff, Disposable, Adult Plus  
98-040C-01, Cuff, Disposable, Large Adult Plus, Box of 20  
98-040E-06, Cuff, Disposable, Neonate 1, 1-Tube  
98-040E-07, Cuff, Disposable, Neonate 1, 2-Tube  
98-040E-08, Cuff, Disposable, Neonate 1  
98-040F-06, Cuff, Disposable, Neonate 2, 1-Tube  
98-040F-07, Cuff, Disposable, Neonate 2, 2-Tube  
98-040F-08, Cuff, Disposable, Neonate 2  
98-040G-06, Cuff, Disposable, Neonate 3, 1-Tube  
98-040G-07, Cuff, Disposable, Neonate 3, 2-Tube  
98-040G-08, Cuff, Disposable, Neonate 3  
98-040H-06, Cuff, Disposable, Neonate 4, 1-Tube  
98-040H-07, Cuff, Disposable, Neonate 4, 2-Tube  
98-040H-08, Cuff, Disposable, Neonate 4  
98-040J-06, Cuff, Disposable, Neonate 5, 1-Tube  
98-040J-07, Cuff, Disposable, Neonate 5, 2-Tube  
98-040J-08, Cuff, Disposable, Neonate 5  
98-040K-01, Cuff, Disposable, Small Adult Plus  
98-0410-01, Cuff, Disposable, Thigh  
98-0410-06, Cuff, Disposable, Thigh, 1-Tube  
98-0410-07, Cuff, Disposable, Thigh, 2-Tube

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

