Declaration of Conformity

SRN:	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA US-MF-000002189	EC REP SRN:	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands NL-AR-000000116
Product Name: #	Orbit K Blood Pressure Cuff Stress100	**Basic** UDI REF	08409351000000STRESS100YY See attachment
Description: **Intended Purpose:**	Orbit K Blood Pressure Cuff The Orbit K Blood Pressure Cuff is intended to be used with the Tango (Tango, Tango+, Tango M2) line of automated Blood Pressure monitors for cardiac stress and exercise testing. The "K" stands for Korotkoff, which indicates that these cuffs have a built-in microphone capable of detecting the "K-sounds" of the patient.		
Classification:	Class I, Rule 1	**Assessment Procedure:**	Annex II and III
Notified Body:	N/A	**Product Marking:**	CE
GMDN Code and Term	34978 - Blood pressure cuff, reusable	**UMDNS Code and Term**	11703- Devices that have an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. These devices are used in conjunction with another device to determine a patient's blood pressure.

This declaration of conformity is issued under the sole responsibility of SunTech Medical Inc. The above system complies with MDR 2017/745 requirements, in accordance with Annex I (General Safety and Performance Requirements), Annex II (Technical Documentation), Annex III (Post-Market Surveillance), and Annex IV (EC Declaration of Conformity), WEEE Directive 2012/19/EU, the RoHS Directive 2015/863/EU. This declaration is supported by the Quality System approval to ISO 13485 issued by Intertek. All supporting documentation is retained at the premises of the manufacturer.

I, the undersigned, declare on the basis of the above information that the system described above is in compliance with the requirements of MDR Directive 2017/745. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

DocuSigned by:
Michael Williams
Signer Name: Michael Williams
Signing Reason: I approve this document
Signing Time: 2/12/2024 | 11:07:40 AM EST
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Reviewed and Approved by: _____ Date: 2/12/2024

Michael Williams, VP OPS/QA/RA

Signed at SunTech Medical, Inc, Morrisville, NC 27560
Document Expiry Date: 12 February 2025 (maximum of 1 year upon release)

Attachment to Declaration of Conformity
Device variants

REF	Description
98-0061-01	Small Adult Cuff, 18 – 27 cm, w/o microphone
98-0061-02	Adult Cuff, 25 – 35 cm, w/o microphone
98-0061-03	Adult Plus Cuff, 27 – 40 cm, w/o microphone
98-0061-05	Large Adult Cuff, 32 – 44 cm, w/o microphone
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	Small Adult Cuff, 18 – 27 cm, with microphone
98-0062-22	Adult Cuff, 25 – 35 cm, with microphone
98-0062-25	Adult Plus Cuff, 27 – 40 cm, with microphone
98-0062-23	Large Adult Cuff, 32 – 44 cm, with microphone
98-0062-34	Small Adult Orbit-K Cuff with Microphone, Bayonet
98-0062-35	Adult Orbit-K Cuff with Microphone, Bayonet

Standards Applied:

Cleaning/Disinfection	ISO 17664:2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
Safety	IEC 80601-2-30:2018	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance of sphygmomanometers
Biocompatibility	EN ISO 10993-1:2018	Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	ISO 10993-10:2021	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation - First Edition
Symbols	ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
Information	ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
Quality System	EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
Risk Management	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices