Declaration of Conformity

(For Britain, Wales & Scotland)

 **SRN:**	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200 suntechmed.com USA US-MF-000002189	UK REP	International Associates Limited Centrum House, 38 Queen Street, Glasgow, Lanarkshire, G1 3DX, UK UKRP@ia-uk.com
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 the requirements set out in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), 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), and with WEEE Directive 2012/19/EU, and the European ROHS Directive 2015/863. 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).

Reviewed and Approved by: DocuSigned by: Randy Evers

Signer Name: Randy Evers
Signing Reason: I approve this document
Signing Time: 10/20/2021 | 10:34:58 AM PDT
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Randy Evers
Regulatory Engineer

Date: 10/20/2021

Signed at SunTech Medical, Inc, Morrisville, NC 27560-8200
Document Expiry Date: 10/20/2022 (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
98-0062-21	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

Standards Applied:

Safety	IEC 80601-2-30:2009 + A1:2013	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance of sphygmomanometers
	EN1060-3: 1997 + A2: 2009	Non-invasive sphygmomanometers-Part 3: Supplementary requirements for electro-mechanical blood
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 10993-10:2010	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
Symbols	ISO 15223-1:2016	Medical Devices – Symbols to Be Used With Medical Device Labels, L Labelling, and Information To Be Supplied - Part 1: General Requirements
Quality System	EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
Risk Management	EN ISO 14971:2012	Medical Devices Risk Analysis