Declaration of Conformity

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	SunTech Medical, Inc.
Business address:	5827 South Miami Blvd, Suite 100, Morrisville, NC 27560
Medical device(s):	Ambulatory Non-Invasive Blood Pressure Monitor, Oscar 2, Model 250
Classification:	IIa
GMDN code and term:	36888 – Blood pressure ambulatory recorder
Scope of application:	99-0133-XX (where -XX indicates any number 00 to 99)
Basic UDI:	08409351000000000000002507E

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	See attached certificate
Design examination certificate (if applicable):	None
Standards applied:	See attached Schedule A

Authorised signatory:

DocuSigned by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 6/20/2022 | 9:05:29 AM PDT
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Tonia E. Bryant, Regulatory Affairs Manager

6/20/2022
Date

Declaration of Conformity – Schedule A

Standards Applied:

Safety	IEC 60601-1: Ed. 3.1 (2012)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Performance/Safety	IEC80601-2-30: Ed. 2.0 (2018)	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
	ISO 80601-2-56:2017	Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
	ISO 80601-2-61: Ed.2.0 (2017)	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
	ISO 81060-1: 2012	Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement
EMC/EMI/ ESD	IEC 60601-1-2: Ed. 4.0 (2014)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
Software	IEC 62304: Ed. 1.1 (2015)	Medical device software – Software life cycle processes
Usability	IEC 60601-1-6:2010 +A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
	EN 62366-1: 2015	Medical devices – Part 1: Application of usability engineering to medical devices
Clinical	IEC 81060-2: 2018	Non-Invasive sphygmomanometers - Part 2 Clinical investigation of intermittent automated measurement type
Biocompatibility (System)	ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	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
Risk Management	ISO 14971:2019	Medical devices — Application of risk management to medical devices
Quality System	ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
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