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):	All Purpose Cuff (APC); One Piece Durable Cuff (OPC)
Classification:	I (non-measuring, non-sterile)
GMDN code and term:	34978 – Blood pressure cuff, reusable
Scope of application:	98-06XX-XX; OPC various sizes, with 1 or 2 tubes, with various connectors and package sizes. (where -XX indicates any alphanumeric character 0 to 9 or A-Z) 98-008X-XX and 98-009X-XX; APC various sizes, with 1 or 2 tubes, with various connectors and package sizes. (where -XX indicates any alphanumeric character 0 to 9 or A-Z)
APC Basic UDI:	08409351000000000222APCF4
OPC Basic UDI:	08409351000000000222OPCHA

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
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Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 6/20/2022 | 8:39:31 AM PDT

Signature

Tonia E. Bryant, Regulatory Affairs Manager

6/20/2022

Date

Declaration of Conformity – Schedule A

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 80601-2-30:2009 + 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 pressure measuring systems
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 15223-1:2021	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