Declaration of Conformity

(For Britain, Wales & Scotland)

 **SRN:**	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA US-MF-000002189		International Associates Limited Centrum House, 38 Queen Street, Glasgow, Lanarkshire, G1 3DX, UK UKRP@ia-uk.com
Product Name: 	Bravo 250D	**Basic**  	08409351000000000250D92 99-0233-XX, (where -XX indicates any number 00 to 99); NJXXX (where -XXX indicates any number 000 to 999).
Description: **Intended Purpose:**	Non-Invasive Ambulatory Blood Pressure device The Oscar 2, Model 250D (Bravo Mini) is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin 4 SE, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult or pediatric (>3yrs) patients' systolic and diastolic blood pressures over an extended period of time. The device is only for measurement, recording, and display. It makes no diagnoses. The device may be worn for up to 24hours.		
Classification:	Class IIa, Rule 10	**Assessment Procedure:**	Annex II (with the exception of section 4)
Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-162 22 Kista Sweden	**Product Marking:**	CE 0413
GMDN Code and Term	36888 - Blood pressure ambulatory recorder	**UMDNS Code and Term**	18364 – Recorder, physiologic, 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 (Essential Requirements), Annex II (EC Declaration of Conformity – Quality System Production), with 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 the Medical Device Directive 93/42/EEC. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

Signed by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 2/25/2025 | 12:13:51 PM PST
74D91508594B47A18C3113C71002CECD

Reviewed and Approved by: _____
Tonia E. Bryant, Director, Regulatory Affairs

Signed at SunTech Medical, Inc, Morrisville, NC 27560

Attachment to Declaration of Conformity

Device variants

REF	Description
99-0233-00	System, M250D ABPM, Standard, 1 Button
99-0233-01	System, M250D ABPM, Standard, 3 Button
99-0233-10	Norav System, M250D ABPM, Standard 3-Button
99-0233-20	DMS 1-btn M250D ABPM
99-0233-30	Bionet, System, M250D ABPM, (Named Lab24)
99-0233-50	Bravo 3-btn M250D ABPM
99-0233-60	BPL, System, M250D ABPM
NJ124	Microport, System, M250D ABPM, Standard 1-Button

Standards Applied:

Safety	IEC 60601-1: Ed. 3.2 (2020)	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 81060-1: 2012	Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement
	IEC 60601-1-11:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EMC/EMI/ ESD	IEC 60601-1-2: 2020	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 +A2:2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
	EN 62366-1: 2015+AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
Clinical	IEC 81060-2:2013	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
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