Declaration of Conformity

SRN:	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA US-MF-000002189	**SRN:**	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands NL-AR-000000116
Product Name: #	Oscar 2 250	**Basic** UDI REF	08409351000000000002507E 99-0133-XX, (where -XX indicates any number 00 to 99)
Description: **Intended Purpose:**	Non-Invasive Ambulatory Blood Pressure device The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro™, 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 and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses. Optionally, the Model 250 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired, but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects). Bluetooth wireless connectivity may be offered as an option.		
Classification:	Class IIa, Rule 10	**Assessment Procedure:**	Annex II (with the exemption 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 Council Directive 93/42/EEC, with LVFS 2003:11 transposing European Medical Devices, amendments to Council Directive 93/42/EEC outlined in Directive 2007/47/EC, in accordance with Annex I (Essential Requirements), Annex II (EC Declaration of Conformity – Quality System Production), the WEEE Directive 2012/19/EU, the European ROHS Directive 2015/863, and the Radio Equipment (RED) Directive (2014/53/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).

Digitally signed by Prodan Sveatoslav
Date: 2023.07.28 08:19:31 EEST
Reason: MoldSign Signature
Location: Moldova

DocuSigned by:
Michael Williams
Signer Name: Michael Williams
Signing Reason: I approve this document
Signing Time: 3/13/2023 | 6:56:38 AM EDT
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Reviewed and Approved by: _____ Date: 3/13/2023
Michael Williams, VP OPS/QA/RA

Signed at SunTech Medical, Inc, Morrisville, NC 27560
Document Expiry Date: 13 March 2024 (maximum of 1 year upon release)

Attachment to Declaration of Conformity

Device variants

REF	Description
99-0133-00	System, Oscar 2, Model 250, Standard
99-0133-01	System, Oscar 2, Model 250, Standard, Bluetooth
99-0133-02	System, Oscar 2, Model 250, Central BP
99-0133-03	System, Oscar 2, Model 250, Central BP, Bluetooth
99-0133-04	System, Oscar 2, Model 250, Standard, China
99-0133-05	System, Oscar 2, Model 250, Standard, Bluetooth, China
99-0133-06	System, Oscar 2, Model 250, Central BP, China
99-0133-07	System, Oscar 2, Model 250, Central BP, Bluetooth, China
99-0133-10	System, Oscar 2, Model 250, Standard, without software
99-0133-11	System, Oscar 2, Model 250, Standard, Bluetooth Without Software
99-0133-12	System, Oscar 2, Model 250, Central BP w/o Software
99-0133-13	System, Oscar 2, Model 250, Central BP, Bluetooth W/O SW
99-0133-20	System, Oscar 2, Model 250, Standard, Brazil
99-0133-21	System, Oscar 2, Model 250, Standard, Bluetooth, Brazil
99-0133-22	System, Oscar 2, Model 250, CBP, Brazil
99-0133-23	System, Oscar 2, Model 250, Central BP, Bluetooth, Brazil
99-0133-30	System, Oscar 2, Model 250, Standard, without software, Brazil
99-0133-40	System, Oscar 2, Model 250, Standard, Macrosul
99-0133-42	System, Oscar 2, Model 250, SphygmoCor, Macrosul
99-0133-43	System, Oscar 2, Model 250, SphygmoCor, BlueTooth, Macrosul

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 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