# Declaration of Conformity

(For Britain, Wales & Scotland)

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|---|---|---|---|
| | SunTech Medical, Inc.<br>5827 South Miami Blvd, Ste 100<br>Morrisville, NC 27560<br>suntechmed.com<br>USA | UK REP | International Associates Limited<br>Centrum House, 38 Queen Street, Glasgow,<br>Lanarkshire, G1 3DX, UK<br>UKRP@ia-uk.com |
| **SRN:** | US-MF-000002189 | | |
| **Product Name:** | Oscar 2 | **Basic** UDI | 08409351000000000002507E |
| # | 250 | REF | 99-0133-XX, (where -XX indicates any number 00 to 99). |
| **Description:** | Non-Invasive Ambulatory Blood Pressure device | | |
| **Intended Purpose:** | 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.<br><br>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 exception of section 4) |
| **Notified Body:** | Intertek Medical Notified Body AB<br>Torshamnsgatan 43, Box 1103<br>SE-162 22 Kista<br>Sweden | **Product Marking:** | CE<br>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 | 12:13:32 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 |
|---|---|
| 99-0133-00 | 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 |

**Standards Applied:**

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| 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 60601-11:2015+AMD 1:2020 | 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: Ed. 4.1 (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 +A1:2013+A2: 2020 | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |
| | EN 62366-1: 2015 +AMD2:2020 | 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 |