# Declaration of Conformity

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|---|---|---|---|
| SRN: | SunTech Medical, Inc.<br>5827 South Miami Blvd, Ste 100<br>Morrisville, NC 27560<br>suntechmed.com<br>USA<br><br>US-MF-000002189 | EC REP<br>SRN: | Emergo Europe<br>Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands<br><br>NL-AR-000000116 |
| **Product Name:**<br># | CT40<br><br>260 | **Basic** UDI<br>REF | 08409351000000000002607H<br><br>See attachment |
| **Description:** | Non-Invasive Oscillometric Spot Check Vital Signs device with optional Temperature and Pulse Oximetry | | |
| **Intended Purpose:** | The SunTech CT40 is a clinical grade, automated blood pressure measurement device with optional temperature and pulse oximetry modules for spot-check vital sign measurements in physician offices, long term care facilities, and low-acuity areas in hospitals. The CT40 can be used in combination with a clinical IT network to transfer and store patient measurement data on an EMR system. | | |
| **Classification:** | Class IIa, Rule 10 | **Assessment Procedure:** | Annex II (with the exemption 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** | 57960 - Multiple physiological parameters spot-check system, clinical | **UMDNS Code and Term** | 16157 - Sphygmomanometers, Electronic |

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).

Signed by:
*Tonia Bryant*
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 2/25/2025 | 12:13:07 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 |
|---|---|
| 99-0134-00 | SunTech CT40 Base unit with BP (no power cord) |
| 99-0134-01 | SunTech CT40 Base unit with BP with AC Power Cord (Americas) |
| 99-0134-02 | SunTech CT40 Base unit with BP with AC Power Cord (Europe) |
| 99-0134-03 | SunTech CT40 Base unit with BP with AC Power Cord (UK) |

**Standards Applied:**

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|---|---|---|
| Safety | IEC 60601-1: Ed. 3.1 (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 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 (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 +A MD1:2013+AMD2: 2020 | 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 |