SunTech Medical®

# Declaration of Conformity

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| Manufacturer: | SunTech Medical, Inc.<br>507 Airport Boulevard, Suite 117<br>Morrisville, NC 27650-8200 |
| EU Rep: | SunTech Medical, Ltd.<br>Oakfield Industrial Estate<br>Stanton Harcourt Road<br>Eynsham, Oxon OX29 4TS<br>United Kingdom |
| Product Name: | CT40 |
| Model Number: | 260 |
| Description: | Non-Invasive Oscillometric Spot Check Vital Signs device with optional Temperature and Pulse Oximetry |
| Classification: | CT40 System: Class IIa, Rule 10<br>OPD Cuff: Class 1, Rule 1 |
| Assessment Procedure: | CT40 System: Annex II (with the exception of section 4)<br>OPD Cuff: Annex VII |
| Notified Body | Intertek Semko AB<br>Box 1103, SE-164 22 Kista,<br>Sweden |
| Product Marking | CE<br>0413 |

The above product and 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/ED, Annex I (Essential Requirements) and Annex II (EC Declaration of Conformity – Quality System Production), and with WEEE Directive 2012/19/EU, the European ROHS Directive 2011/65/EU, and the Radio Equipment (RED) Directive (2014/53/EU).

I, the undersigned, declare on the basis of the above information that the system described above is in compliance with the requirements of Directive 93/42/EEC. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

Reviewed and Approved by: Mike Taggart Date: 1/2/19

Mike Taggart
Director, Quality and Regulatory