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 |
| Device | CT40, Model 260 Non-Invasive Oscillometric Spot Check Vital Signs device with optional Temperature and Pulse Oximetry |
| Product Class | Class IIa |
| Assessment Procedure | Annex II |
| Notified Body | Intertek Semko AB<br>Box 1103, SE-164 22 Kista,<br>Sweden |
| Product Marking | CE<br>0413 |

We hereby declare that the above mentioned product, including system components and accessories, complies with LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC WEEE – Directive 2002/96/EC, with the applicable portions of European ROHS Directive 2011/65/EU, R&TTE (1999/5/EC) Directive, and the following standards and normative documents:

1. EN 60601-1:2006/A1:2013, Medical electrical equipment Part 1: General requirements for safety.

2. IEC 60601-1-2:2007, Medical electrical equipment – Part 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

3. EN ISO 81060-1: 2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

4. IEC 60601-1-6: 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

5. EN 62366: 2008 Medical devices - Application of usability engineering to medical devices



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6. IEC 80601-2-30: 2009 +A1:2013 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

7. ISO 80601-2-56: 2009 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

8. ISO 80601-2-61: 2011 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

9. ISO 81060-2:2013 Non-invasive sphygmomanometers —Part 2: Clinical investigation of automated measurement type

10. ISO 15223-1: 2012 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements

11. ISO 10993-1:2009/AC: 2010, Biological evaluation of medical devices, Part 1; Evaluation and testing.

12. ISO 10993-5:2009, Biological evaluation of medical devices, Part 5 – Test for in vitro cytotoxicty.

13. ISO 10993-10:2010, Biological evaluation of medical devices, Part 10 – Tests for irritation and delayed-type hypersensitivity.

14. EN 50419: 2006 Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)

15. EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

16. EN ISO 13485: 2012 Medical Devices – Quality management systems – Requirements for regulatory purposes.

Valid on and after: January 29, 2016

Name: Chuck Setzer
Position: Quality and Regulatory Affairs Manager
Company: SunTech Medical, Inc.



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