SunTech Medical®

Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27650-8200
EU Rep	SunTech Medical, Ltd. Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxon OX29 4TS United Kingdom
Device	247 Non-invasive Blood Pressure device with optional Temperature and Pulse Oximetry
Product Class	Class IIa
Assessment Procedure	Annex II
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	CE 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 and the following standards and normative documents:

1. IEC 60601-1:1988 + A1:1991 + A2: 1995, Medical electrical equipment Part 1 : General requirements for safety. (including national differences)
2. IEC 60601-1-2:2001, Medical electrical equipment – Part 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
3. IEC 60601-1-4: 1996 +Am1:1999, Medical electrical equipment part 1-4 Collateral Standard: Programable electrical medical systems
4. EN 1060-1:1995, Specification for non-invasive sphygmomanometers – Part 1: General requirements
5. EN 1060-3:1997, Non-invasive sphygmomanometers – Part 3. Supplementary Requirements for Electro-Mechanical BP Measuring Systems.
6. ISO 9919:1992, Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
7. EN 980 :2008, Symbols for use in the labeling of medical devices.
8. EN 1041 :2008, Information supplied by the manufacturer of medical devices.

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9. ISO 10993-1:2009, Biological evaluation of medical devices, Part 1; Evaluation and testing.
10. ISO 10993-5:2009, Biological evaluation of medical devices, Part 5 – Test for in vitro cytotoxicty.
11. ISO 10993-10:2010, Biological evaluation of medical devices, Part 10 – Tests for irritation and delayed-type hypersensitivity.
12. FDA 21CFR801.5, Medical devices ; adequate directions for use.
13. AMMI SP10:2008, Electronic or Automated Sphygmomanometers
14. WEEE – Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) – Joint declaration of the European Parliament, the Council and the Commission relating to Article 9 (Official Journal L 037, 13/02/2003).

Valid on and after: August 16, 2011

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