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	Kadenz ™ OEM NIBP Module Series
Product Class	N/A, OEM module
Assessment Procedure	N/A
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	N/A Module not marked

We hereby declare that the above mentioned module complies with the applicable portions of LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC, and with the applicable portions of European ROHS Directive 2011/65/EU, and with the applicable portions of the following standards and normative documents:

1. IEC 60601-1:1988 + A1:1991 + A2: 1995, Medical electrical equipment Part 1 : General requirements for safety.
2. IEC 60601-2-30:1999, Medical electrical equipment – Part 2: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.
3. IEC 60601-1-2:2001, Medical electrical equipment – Part 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
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. EN 1060-4:2004, Non-invasive Sphygmomanometers-Part 4 Test Procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
7. ISO 10993-1:2009, Biological Evaluation of Medical Devices- Guidance on the Selection of Test
8. ISO 10993-5:2009, Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity

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9. ISO 10993-10:2010, Biological Evaluation of Medical Devices-Tests for Irritation and Sensitization
10. ISO 14971:2007, Medical Devices – Application of risk management to medical devices
11. EN1041:2008, Specifications for Information supplied by the Manufacturer of Medical Devices
12. AMMI SP10:2008, Electronic or Automated Sphygmomanometers

Valid on and after: 29July2014

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