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: 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
Box 1103, SE-164 22 Kista, Sweden

Product Marking: 

P413


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
Declaration of Conformity


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


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


Valid on and after: January 29, 2016

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