

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


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
OPD Cuff: Class 1, Rule 1

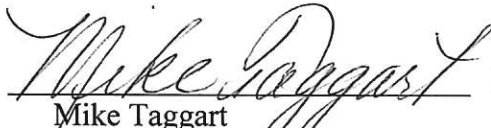
Assessment Procedure: CT40 System: Annex II (with the exception of section 4)
OPD Cuff: Annex VII

Notified Body Intertek Semko AB
Box 1103, SE-164 22 Kista,
Sweden

Product Marking 
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:  Date: 4/2/19
Mike Taggart
Director, Quality and Regulatory