SunTech Medical®

Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200 suntechmed.com USA
EU Rep:	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name:	CT50 Vital Signs Monitor
Model Number:	270
Description:	Non-invasive oscillometric blood Pressure monitoring device with optional temperature and pulse oximetry
Classification:	CT50 Vital Signs Monitor: Class IIb, Rule 10
Assessment Procedure:	CT50 Vital Signs Monitor: Annex II (with the exception of section 4)
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	CE 0413

The above CT50 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/EC, Annex I (Essential Requirements) and Annex II (EC Declaration of Conformity – Quality System Production) (with the exception of section 4), and with WEEE Directive 2002/96/EC, and the European ROHS Directive 2011/65/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 as indicated. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

Reviewed and Approved by: Ravi Kommineni

Ravi Kommineni
Director of QA/RA

Date: 23 JUNE 2020