SunTech Medical®

Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27650-8200 suntechmed.com
EU Rep:	SunTech Medical, Ltd. Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxon OX29 4TS United Kingdom
Product Name:	Oscar 2
Model Number:	250
Description:	Non-Invasive Ambulatory Blood Pressure Monitor and Accuwin Pro V4 Software
Classification:	Oscar 2 System: Class IIa, Rule 10 Orbit ABPM Cuff: Class 1, Rule 1
Assessment Procedure	Oscar 2 System: Annex II (with the exception of section 4) Orbit ABPM Cuff: Annex VII
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	CE 0413

The above product and system comply 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, and with the European ROHS Directive 2011/65/EU.

I, the undersigned, declare based on 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: Mike Taggart Date: 1/21/19

Mike Taggart
Director, Quality and Regulatory