

Declaration of Conformity

Manufacturer: SunTech Medical, Inc.
507 Airport Boulevard, Suite 117
Morrisville, NC 27650-8200
suntechmed.com

EU Rep: EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Product Name: Oscar 2

Model Number: 250D

Description: Non-Invasive Ambulatory Blood Pressure Monitor and AccuWin Pro V4 Software

Classification: Oscar 2 System: Class IIa, Rule 10


Assessment Procedure Oscar 2 System: 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 Oscar 2 ABPM 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), and with WEEE Directive 2002/96/EC, and with 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. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

Reviewed and Approved by: 
Ravi Kommineni
Director of QA/RA

Date: 23 JUNE 2020