

Declaration of Conformity

Manufacturer: SunTech Medical, Inc.
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Morrisville, NC 27650-8200
suntechmed.com
USA

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

UK Responsible Person: International Associates Limited
Established in: Scotland, UK
Address: 1n, 38 Queen Street
Glasgow
G1 3DX
Scotland,
UK
Martin Coles martin@ia-uk.com 0141 3 28 29 28

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

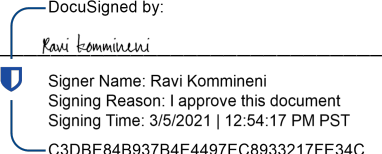
Assessment Procedure Oscar 2 System: Annex II (with the exception of section 4)

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

Product Marking 
0413

The above Oscar 2 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 2012/19/EU, and with the European ROHS Directive 2011/65/EU, as amended by 2015/863/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:  DocuSigned by:
Ravi Kommineni
Date: 3/5/2021
Ravi Kommineni
Director of QA/RA

Signer Name: Ravi Kommineni
Signing Reason: I approve this document
Signing Time: 3/5/2021 | 12:54:17 PM PST
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