Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27650-8200 suntechmed.com USA
EU Rep:	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
UK Responsible Person: Established in: Address:	International Associates Limited Scotland, UK 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	CE 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

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

Ravi Kommineni
Director of QA/RA