SUNTECH

Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 5827 South Miami Boulevard, Suite 100 Morrisville, NC 27650-8394 suntechmed.com
EU Rep:	EMERGO Europe Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name:	NBP One
Model Number:	250D
Description:	Non-Invasive Ambulatory Blood Pressure Monitor and AccuWin Pro V4 Software
Classification:	NBP One System: Class IIa, Rule 10 Orbit ABPM Cuff: Class 1, Rule 1
Assessment Procedure	NBP One System: Annex II Orbit ABPM Cuff: Annex VII
Notified Body	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-162 22 Kista Sweden
Product Marking	CE 0413

The above NBP One 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/ED, 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).

DocuSigned by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 7/26/2022 | 10:28:51 AM PDT

Reviewed and Approved by: _____ Date: 7/26/2022
Tonia E. Bryant, Regulatory Affairs Manager 4B47A18C3113C71002CECD

Digitally signed by Prodan Sveatoslav
Date: 2023.03.31 09:59:53 EEST
Reason: MoldSign Signature
Location: Moldova

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