

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: 
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: Tonia E. Bryant, Regulatory Affairs Manager
ID: 4B47A18C3113C71002CECD

7/26/2022

Date: _____

