

## 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


Product Name: ABPM Orbit Cuff

Model Number: ABPM200

Description: Non-Invasive Blood Pressure Cuff


Classification: Class 1, Rule 1

Assessment Procedure: Annex VII

Product Marking 

The above product 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 VII (EC Declaration of Conformity – Quality System Production), and with the 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