SunTech Medical®

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:	Bravo Mini
Model Number:	250D
Description:	Non-Invasive Ambulatory Blood Pressure Monitor and AccuWin Pro V4 Software
Classification:	Bravo Mini System: Class IIa, Rule 10
Assessment Procedure	Bravo Mini System: Annex II
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	CE 0413

The above Bravo Mini 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/EC, 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).

Reviewed and Approved by: Ravi Kommineni

Ravi Kommineni
Director of QA/RA

Date: 23 JUNE 2020