SunTech Medical®

Declaration of Conformity

Manufacturer:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27650-8200
EU Rep:	SunTech Medical, Ltd. Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxon OX29 4TS United Kingdom
Product Names:	All Purpose Cuff (APC) and One Piece Durable Cuff (OPD)
Model Numbers:	APC: 222APC OPD: 222OPD
Classification	Class 1, Rule 1
Assessment Procedure	Annex VII
Notified Body	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden
Product Marking	CE

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/ED, Annex I (Essential Requirements) and Annex VII (EC Declaration of Conformity – Quality System Production), and with the applicable requirements of 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: _____ Date: 9-01-2017

Rebecca Hudson
Director, Regulatory Affairs and Quality Assurance