

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

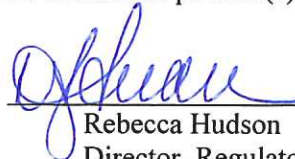
Notified Body Intertek Semko AB
Box 1103, SE-164 22 Kista,
Sweden

Product Marking 

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:


Rebecca Hudson
Director, Regulatory Affairs and Quality Assurance

Date:

9-01-2017