SunTech Medical®

# Declaration of Conformity

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| Manufacturer: | SunTech Medical, Inc.<br>507 Airport Boulevard, Suite 117<br>Morrisville, NC 27650-8200 |
| EU Rep: | SunTech Medical, Ltd.<br>Oakfield Industrial Estate<br>Stanton Harcourt Road<br>Eynsham, Oxon OX29 4TS<br>United Kingdom |
| Product Names: | Disposable and Vinyl Non-Invasive Pressure Cuffs |
| Model Numbers: | Disposable Cuff: DC100<br>Vinyl Cuff: VC100 |
| Classification: | Class 1, Rule 1 |
| Assessment Procedure: | Annex VII |
| Notified Body: | Intertek Semko AB<br>Box 1103, SE-164 22 Kista,<br>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