




# Declaration of Conformity

(For Britain, Wales & Scotland)

  SRN:	SunTech Medical, Inc. 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200 suntechmed.com USA		International Associates Limited Centrum House, 38 Queen Street, Glasgow, Lanarkshire, G1 3DX, UK UKRP@ia-uk.com
<b>Product Name</b>  #	ABPM Orbit Cuff  ABPM200	<b>Basic UDI</b>  <b>REF</b>	0840935100000000ABPM20078  See attachment
<b>Description:</b>  <b>Intended Purpose:</b>	Non-Invasive Ambulatory Blood Pressure Cuff  The ABPM Orbit Blood Pressure Cuff is intended to be used with a non-invasive blood pressure measurement system to determine blood pressure parameters on pediatric and adult patients. It is to be used with a SunTech Medical Ambulatory Blood Pressure System or with an OEM blood pressure monitoring device.		
<b>Classification:</b>	Class I, Rule 1	<b>Assessment Procedure:</b>	Annex II and III
<b>Notified Body:</b>	N/A	<b>Product Marking:</b>	
<b>GMDN Code and Term</b>	34978 - Blood pressure cuff, reusable	<b>UMDNS Code and Term</b>	11703- Devices that have an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. These devices are used in conjunction with another device to determine a patient's blood pressure.

This declaration of conformity is issued under the sole responsibility of SunTech Medical Inc. The above system complies with the requirements set out in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), in accordance with Annex I (General Safety and Performance Requirements), Annex II (Technical Documentation), Annex III (Post-Market Surveillance), and Annex IV (EC Declaration of Conformity) and the European ROHS Directive 2015/863. This declaration is supported by the Quality System approval to ISO 13485 issued by Intertek. All supporting documentation is retained at the premises of the manufacturer.

I, the undersigned, declare on the basis of the above information that the system described above is in compliance with the requirements of MDD Directive 93/42/EEC. This declaration hereby authorizes the UKCA Mark to be affixed to the above-mentioned product(s).

Reviewed and Approved by: Randy Evers Date: 10/20/2021  
 Randy Evers  
 Regulatory Engineer

DocuSigned by:  
 Signer Name: Randy Evers  
 Signing Reason: I approve this document  
 Signing Time: 10/20/2021 | 10:35:08 AM PDT  
 C7B4F1E9CA084CBFB500A9ED713EC301

Signed at SunTech Medical, Inc, Morrisville, NC 27560-8200

Document Expiry Date: 10/20/2022 (maximum of 1 year upon release)

## Attachment to Declaration of Conformity

<b>REF</b>	<b>Description</b>
98-0239-01	ABPM Cuff Size 1
98-0239-02	ABPM Cuff Size 2
98-0239-03	ABPM Cuff Size 3
98-0239-04	ABPM Cuff Size 4

### Standards Applied:

Safety	IEC 80601-2-30:2009 + A1:2013	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance of sphygmomanometers
	EN1060-3: 1997 + A2: 2009	Non-invasive sphygmomanometers-Part 3: Supplementary requirements for electro-mechanical blood
Biocompatibility	EN ISO 10993-1:2018	Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	ISO 10993-10:2010	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
Symbols	ISO 15223-1:2021	Medical Devices – Symbols to Be Used With Medical Device Labels, L Labelling, and Information To Be Supplied - Part 1: General Requirements
Quality System	EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
Risk Management	EN ISO 14971:2012	Medical Devices Risk Analysis