Declaration of Conformity

SRN:	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA US-MF-000002189	**SRN:**	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands NL-AR-000000116
Product Name: #	All Purpose Cuff (APC) One Piece Durable Cuff (OPC) APC: 222APC OPC: 222OPC	**APC Basic** UDI UDI REF	08409351000000000222APCF4 08409351000000000222OPCHA See attachment
Description: **Intended Purpose:**	All Purpose and One-Piece Durable Blood Pressure Cuffs The All-Purpose Cuffs and One-Piece Durable Cuffs are intended to be used with a manual or automatic non-invasive sphygmomanometer to determine blood pressure parameters on pediatric and adult patients. These cuffs are not intended to be used on neonates. These cuffs are intended to be used with prescription (clinical grade) blood pressure monitors or with over-the counter (home) blood pressure monitors.		
Classification:	Class I, Rule 1	**Assessment Procedure:**	Annex II and III
Notified Body:	N/A	**Product Marking:**	CE
GMDN Code and Term	34978 - Blood pressure cuff, reusable	**UMDNS Code and Term**	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 MDR 2017/745 requirements, 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), WEEE Directive 2012/19/EU, the RoHS Directive 2015/863/EU. 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 MDR Directive 2017/745. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

Signed by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 2/25/2025 | 12:12:29 PM PST
74D91508594B47A18C3113C71002CECD

Reviewed and Approved by: _____
Tonia E. Bryant, Director, Regulatory Affairs

Signed at SunTech Medical, Inc, Morrisville, NC 27560

Attachment to Declaration of Conformity

Device variants

REF	Description
98-06XX-XX	On Piece Durable Cuff, various sizes, with 1 or 2 tubes, with various connectors and package sizes. (where -XX indicates any alphanumeric character 0 to 9 or A-Z)
98-008X-XX	All Purpose Cuff, various sizes, with 1 or 2 tubes, with various connectors and package sizes. (where -XX indicates any alphanumeric character 0 to 9 or A-Z)
98-009X-XX	
98-01XX-XX	
98-00XX-XX	

Standards Applied:

Cleaning/Disinfection	ISO 17664:2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
Safety	IEC 80601-2-30:2018	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance of sphygmomanometers
Biocompatibility	EN ISO 10993-1:2018	Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process
Symbols	ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
Information	ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
Quality System	EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
Risk Management	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices