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 Prinsessegracht 20 2514 AP The Hague The Netherlands NL-AR-000000116
Product Name: #	Disposable Blood Pressure Cuff and Single Patient Use Kits DC100	**Basic** UDI REF	0840935100000000000DC100H9 98-040X-XX and 98-0700-XX (where X and -XX indicates any alphanumeric character 0 to 9 or A-Z)
Description: **Intended Purpose:**	Disposable Blood Pressure Cuff The Disposable Blood Pressure cuff is intended to be used with non-invasive blood pressure measurement systems to determine blood pressure parameters on neonate, pediatric and adult patients. The Disposable Blood Pressure Cuff is single patient use, to assist with infection control measures. Single Patient Use (SPU) Kits contain a Disposable Cuff with an adhesive pad.		
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).

DocuSigned by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 7/28/2022 | 10:00:12 AM PDT
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Reviewed and Approved by: _____ Date: 06/20/2022
Tonia E. Bryant, Manager, Regulatory Affairs

Signed at SunTech Medical, Inc, Morrisville, NC 27560
Document Expiry Date: 20 June 2023 (maximum of 1 year upon release)

Attachment to Declaration of Conformity

Device variants

REF	Description
98-040X-XX	Disposable Cuff, various sizes, with 1 or 2 tubes, with various connectors and package sizes. (where X and -XX indicates any alphanumeric character 0 to 9 or A-Z)
98-0700-XX	Single Patient Use Kits (where -XX indicates any alphanumeric character 0 to 9 or A-Z)

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 80601-2-30:2009 + 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 pressure measuring systems
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 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