Declaration of Conformity

	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA	EC REP	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands
SRN:	US-MF-000002189	**SRN:**	NL-AR-000000116
Product Name:	CT40	**Basic** UDI	08409351000000000002607H
#	260	REF	See attachment
Description:	Non-Invasive Oscillometric Spot Check Vital Signs device with optional Temperature and Pulse Oximetry		
Intended Purpose:	The SunTech CT40 is a clinical grade, automated blood pressure measurement device with optional temperature and pulse oximetry modules for spot-check vital sign measurements in physician offices, long term care facilities, and low-acuity areas in hospitals. The CT40 can be used in combination with a clinical IT network to transfer and store patient measurement data on an EMR system.		
Classification:	Class IIa, Rule 10	**Assessment Procedure:**	Annex II (with the exemption of section 4)
Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-162 22 Kista Sweden	**Product Marking:**	CE 0413
GMDN Code and Term	57960 - Multiple physiological parameters spot-check system, clinical	**UMDNS Code and Term**	16157 - Sphygmomanometers, Electronic

This declaration of conformity is issued under the sole responsibility of SunTech Medical Inc. The above system 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/EC, in accordance with Annex I (Essential Requirements), Annex II (EC Declaration of Conformity – Quality System Production), the WEEE Directive 2012/19/EU, the European ROHS Directive 2015/863, and the Radio Equipment (RED) Directive (2014/53/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 the Medical Device Directive 93/42/EEC. This declaration hereby authorizes the CE Mark to be affixed to the above-mentioned product(s).

DocuSigned by:
Michael Williams
Signer Name: Michael Williams
Signing Reason: I approve this document
Signing Time: 2/12/2024 | 9:27:31 AM EST
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2/12/2024

Reviewed and Approved by: _____ Date: _____
Michael Williams, VP OPS/QA/RA

Signed at SunTech Medical, Inc, Morrisville, NC 27560
Document Expiry Date: 12 February 2025 (maximum of 1 year upon release)

Attachment to Declaration of Conformity

Device variants

REF	Description
99-0134-00	SunTech CT40 Base unit with BP (no power cord)
99-0134-01	SunTech CT40 Base unit with BP with AC Power Cord (Americas)
99-0134-02	SunTech CT40 Base unit with BP with AC Power Cord (Europe)
99-0134-03	SunTech CT40 Base unit with BP with AC Power Cord (UK)

Standards Applied:

Safety	IEC 60601-1: Ed. 3.1 (2012)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Performance/Safety	IEC80601-2-30: Ed. 2.0 (2018)	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
	ISO 80601-2-56:2017	Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
	ISO 80601-2-61: Ed.2.0 (2017)	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
	ISO 81060-1: 2012	Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement
EMC/EMI/ ESD	IEC 60601-1-2: Ed. 4.0 (2014)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
Software	IEC 62304: Ed. 1.1 (2015)	Medical device software – Software life cycle processes
Usability	IEC 60601-1-6:2010 +A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
	EN 62366-1: 2015	Medical devices – Part 1: Application of usability engineering to medical devices
Clinical	IEC 81060-2: 2013	Non-Invasive sphygmomanometers - Part 2 Clinical investigation of intermittent automated measurement type
Biocompatibility (System)	ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	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
Risk Management	ISO 14971:2019	Medical devices — Application of risk management to medical devices
Quality System	ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
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