Declaration of Conformity

(For Britain, Wales & Scotland)

SRN:	SunTech Medical, Inc. 5827 South Miami Blvd, Ste 100 Morrisville, NC 27560 suntechmed.com USA US-MF-000002189	UK REP	International Associates Limited Centrum House, 38 Queen Street, Glasgow, Lanarkshire, G1 3DX, UK UKRP@ia-uk.com
Product Name: #	Blood Pressure Hoses H100	UDI **Basic** REF	08409351000000000H100BT See attachment
Description: **Intended Purpose:**	Blood Pressure Hose The hose is intended to be used in the assembly of a blood pressure measurement system. The hose provides a pneumatic connection between a blood pressure cuff to its parent blood pressure device.		
Classification:	Class I, Rule I	**Assessment Procedure:**	Annex II and III
Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-162 22 Kista Sweden	**Product Marking:**	CE
GMDN Code and Term	61228 – External cuff/pad connection tubing	**UMDNS Code and Term**	15285 – Tubing, other

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 (Essential Requirements), Annex II (EC Declaration of Conformity – Quality System Production), with 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 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:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 6/20/2022 | 8:16:39 AM PDT
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Reviewed and Approved by: _____ Date: 6/20/2022
Tonia E. Bryant, Manager, Regu

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
91-0028-00	Patient Hose, 3 Meter, Rectus Fittings, Distributor: CN Systems Medizintechnik GmbH
91-0028-02	Patient Hose, 1.2 meter, Black, RDT
91-0028-03	Patient Hose, 11 feet uncoiled, Male CPC on each end, Telemedic Systems
91-0028-06	Patient Hose Assembly, IGEL
91-0028-08	Patient Hose Assembly, Cheetah Medical
91-0028-09	Coiled Back Hose, Male Quick Connect to Straight Locking, 11ft (3.4m)
91-0028-11	Straight Black Hose, Male Quick Connect to Male Quick Connect, 9.8ft (3m)
91-0028-12	Straight Black Hose, Female Quick Connect to Female Luer, 4in (0.1m)
91-0028-13	Straight Black Hose, Male Quick Connect to Female Luer, 9.8ft (3m)
91-0028-14	Straight Black Hose, Straight Locking R/A to Female Luer, 9.8ft (3m)
91-0028-15	Patient Hose Adapter, 4 inches, with Male Bayonet (Metal) and Female Slip Luer (Plastic)
91-0028-16	Straight Black Hose, Female Bayonet to Female Bayonet, 10ft (3m)
91-0028-17	Straight Black Hose, Male Quick Connect to Male Bayonet Metal, 9.8ft (3m)
91-0028-18	Patient Hose Adapter, 4", Threaded (Screw) to Metal Female Bayonet Coupling
91-0028-19	Straight Black Hose, Male Quick Connect to Female Bayonet, 4.9ft (1.5m)
91-0028-21	Straight Gray Hose, Female Luer to Female Bayonet, 9.8ft (3m)
91-0028-51	Straight Black Hose, Female Bayonet to Female Bayonet, 9.8ft (3m)
91-0028-68	Straight Black Hose, Female Quick Connect to Female Quick Connect, 4ft (1.2m)
91-0028-69	Straight Black Hose, Male Quick Connect to Female Bayonet, 9.8ft (3m)
91-0028-70	Patient Hose, 8 feet, with Male Quick Connect and Male Inline Right Angle Push-in connector
91-0028-73	Straight Black Hose, Male Quick Connect to Straight Locking, 6.6ft (2m)
91-0028-74	Patient Hose, 1 Meter, Black, Female Slip Luer, Female CPC
91-0028-87	Patient Hose, 3m, Bayonet-Female Connector
91-0028-88	Patient BP hose, Female Rectus Bayonet to Female Rectus Bayonet
91-0028-89	Patient Hose, 3m, Female Rectus Bayonet to MQC

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
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
	ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation – First Edition
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
Sphygmomanometers	IEC 80601-2-30:2018	Medical Electrical Equipment – Part 2-30: Particular Requirements for the Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers
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