# Declaration of Conformity

**MANUFACTURER'S DECLARATION OF CONFORMITY**

*AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

**FULL QUALITY ASSURANCE PROCEDURES**

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

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|---|---|
| **Manufacturer's name:** | SunTech Medical, Inc. |
| **Business address:** | 5827 South Miami Blvd, Suite 100, Morrisville, NC 27560 |
| **Medical device(s):** | Eclipse (D-Ring) Cuff |
| **Classification:** | I (non-measuring, non-sterile) |
| **GMDN code and term:** | 34978 – Blood pressure cuff, reusable |
| **Scope of application:** | 98-0068-XX (where -XX indicates any number 00 to 99) |
| **Basic UDI:** | 08409351000000000SELF100EX |

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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| **Full quality assurance procedures certificate:** | See attached certificate |
| **Design examination certificate (if applicable):** | None |
| **Standards applied:** | See attached Schedule A |

**Authorised signatory:**

DocuSigned by:
Tonia Bryant
Signer Name: Tonia Bryant
Signing Reason: I approve this document
Signing Time: 6/20/2022 | 8:30:02 AM PDT
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Signature
Tonia E. Bryant, Regulatory Affairs Manager

6/20/2022
Date

**Declaration of Conformity – Schedule A**

**Standards Applied:**

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|---|---|---|
| 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 |