

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SunTech Medical Inc.

(F000972)

Main Site: 5827 S Miami Blvd Suite 100

Morrisville, North Carolina 27560 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

The design, manufacture, distribution, and service of patient monitoring products (blood pressure, SpO₂, temperature), accessories and related OEM modules.

Certificate Number:

0068171-05

Initial Certification Date:

2017-11-28

Certification Effective Date:

2024-07-05

Certification Expiry Date:

2025-11-27



intertek

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