

# 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:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**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:**

0068171-04

**Initial Certification Date:**

2017-11-28

**Certification Effective Date:**

2022-11-28

**Certification Expiry Date:**

2025-11-27



A handwritten signature in black ink, appearing to read "Calin Moldoveanu", is written over a horizontal line.

**Calin Moldoveanu**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851

