

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SunTech Medical Inc.

Main Site: 507 Airport Boulevard, Suite 117, Morrisville, North Carolina 27560-8200 United States
DUNS #060477028

has been registered by Intertek, an MDSAP recognised auditing organisation, 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:

0068171-02

Initial Certification Date:

2017-10-18

Certificate Effective Date:

2020-08-21

Certificate Expiry Date:

2023-10-17



Calin Moldovean

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