



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 065690 0015 Rev. 04

Holder of Certificate: **Solaris Medical Technology, Inc.**
Zhongjian Industrial Building One #401
18 Yanshan Road, Shekou
Nanshan District
518067 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Sales of Multi-compatible SpO2 Sensors, Vital Signs Monitor; Pulse Oximeter, ECG trunk cable and lead wires, Temperature probe, NIBP cuff.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 065690 0015 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_065690_0015_Rev_04)

Report No.: BJ25095701

Valid from: 2026-02-20

Valid until: 2029-02-19

Date, 2026-01-12

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Solaris Medical Technology, Inc.**
Zhongjian Industrial Building One #401, 18 Yanshan Road,
Shekou, Nanshan District, 518067 Shenzhen, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Sales of Multi-
compatible SpO2 Sensors, Vital Signs Monitor, Pulse Oximeter,
ECG trunk cable and lead wires, Temperature probe, NIBP cuff.

Solaris Medical Technology, Inc. (Dongguan Branch Facility)
5F Building A, No.7 Lane 5, Minchang Road, Nance Five District,
Humen Town, 523000 Dongguan, Guangdong, PEOPLE'S
REPUBLIC OF CHINA

Production of Multi-compatible SpO2 Sensors, ECG trunk cable
and lead wires, Temperature probe, NIBP cuff.