



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 13 12 65690 010

**Manufacturer:****Solaris Medical Technology, Inc.**

Zhongjian Industrial Building One, #301  
18 Yanshan Road, Shekou, Nanshan District  
518067 Shenzhen, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:****Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):**

Multi-compatible SpO2 Sensors,  
Vital Signs Monitor, Pulse Oximeter.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

BJ1395707

**Valid from:**

2014-04-21

**Valid until:**

2019-04-20



Hans-Heiner Junker

**Date,** 2014-01-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 13 12 65690 010**

**Facility(ies):**

Solaris Medical Technology, Inc.  
Zhongjian Industrial Building One, #301, 18 Yanshan Road,  
Shekou, Nanshan District, 518067 Shenzhen, Guangdong,  
PEOPLE'S REPUBLIC OF CHINA



Product Service

# CERTIFICATE

No. Q1N 13 12 65690 009

**Holder of Certificate:** **Solaris Medical Technology, Inc.**

Zhongjian Industrial Building One, #301  
18 Yanshan Road, Shekou, Nanshan District  
518067 Shenzhen, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Solaris Medical Technology, Inc.  
Zhongjian Industrial Building One, #301, 18 Yanshan Road,  
Shekou, Nanshan District, 518067 Shenzhen, Guangdong,  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

**Scope of Certificate:**

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

**Applied  
Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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). See also notes overleaf.

**Report No.:** BJ1395704-1

**Valid from:** 2014-02-21

**Valid until:** 2017-02-20

Hans-Heiner Junker


**Date,** 2014-02-26

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