ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

189395

Date, 2014-01-07

Hans-Heiner Junker

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

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Facility(ies):

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

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