



APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60007997 0001

Report No.: 17001721 001

Manufacturer: Solaris Medical Technology, Inc.
6/F Building 9, 30th District,
Keji Road, Science Park,

Shenzhen, Guangdong 518057
China

Scope: Manufacturing and Sales of Multiple-Compatible
SPO2 Finger Sensors

Date of Expiry: 20.04.2009

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Dipl.-Ing. D. Meier

Cologne, 21.04.2004



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

C E R T I F I C A T E

for a

Quality Management System

according to

ISO 13485:2003

TÜV Rheinland Product Safety GmbH hereby certifies that the

Organization: **Solaris Medical Technology, Inc.**
 6/F Building 9, 30th District,
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has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.
The organization is subject to a yearly surveillance audit.

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Scope: see attachment

Certification Body

Cologne, 21.04.2004




Dipl.-Ing. D. Meier

TÜV Rheinland
Product Safety GmbH

Doc. 1/1, Rev. 0

Am Grauen Stein, D-51105 Köln

Attachment to
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