ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 083562 0017 Rev. 00

Manufacturer: **Spacelabs Healthcare, Inc.**
35301 SE Center Street
Snoqualmie WA 98065
USA

EC-Representative: **MediMark Europe Sarl**
11, Rue Emile Zola - BP 2332, 38033 Grenoble Cedex 2,
FRANCE

Product Category(ies): **Medical Physiological Monitors, Clinical Information Systems**

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.: 72145570

Valid from: 2019-04-24
Valid until: 2019-10-15

Date, 2019-04-24

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Spacelabs Healthcare, Inc.
35301 SE Center Street, Snoqualmie WA 98065, USA

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