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 15 09 83562 013

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

EC-Representative:
Spacelabs Healthcare Ltd.
43 Moray Place
Edinburgh
Lothian EH3 6BT
UNITED KINGDOM

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.: 72108545

Valid from: 2015-10-15
Valid until: 2019-10-15

Date, 2015-10-19

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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