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 17 01 70231 011

Manufacturer:

Spacelabs Healthcare Ltd.
Unit B, Foxholes Centre
John Tate Road
Hertford
Hertfordshire SG13 7DT
UNITED KINGDOM

Product Category(ies):

ECG Recorders, ECG Analysers, Ambulatory NIBP recorders, Cardiac Information Management Systems, ECG Receiving System, ECG Stress Test Systems, Anaesthetic Machines, Anaesthetic Vaporisers and Circle Absorbers

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.: 75937670

Valid from: 2017-02-12
Valid until: 2022-02-11

Date, 2017-02-03

Stefan Preiß

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

TÜV®

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Facility(ies):

Spacelabs Healthcare Ltd.
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