DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 070231 0016 Rev. 00

Holder of Certificate: **Spacelabs Healthcare Ltd.**
Unit B, Foxholes Centre
John Tate Road
Hertford, Hertfordshire SG13 7DT
UNITED KINGDOM

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, production, distribution, repair and service of ECG recorders, ambulatory ECG and NIBP recorders and receiving stations, ECG analysers, ECG stress test systems, Cardiac Information Management Systems, Anaesthetic and Ventilation equipment. Distribution and Servicing of patient monitoring systems.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 75943722

Valid from: 2019-07-15
Valid until: 2021-02-19

Date, 2019-07-15

Stefan Preiß
Head of Certification/Notified Body

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

A4 / 07.17

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

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TÜV SÜD
Product Service

Certificate

No. Q5 070231 0016 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Spacelabs Healthcare GmbH (Germany)
Südwestpark 40, 90449 Nürnberg, GERMANY

Spacelabs Healthcare S.r.l. (Italy)
Viale del Lavoro 33, 37135 Verona, ITALY

Spacelabs Healthcare SAS (France)
20, rue Eugène Dupuis, Europarc – Nano, 94043 Créteil Cedex, FRANCE

Spacelabs Healthcare Ltd.
43 Moray Place, Edinburgh, Lothian EH3 6BT, UNITED KINGDOM

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