



# Certificate

No. Q5 070231 0025 Rev. 00

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

**Certification Mark:**



**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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 070231 0025 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_070231_0025_Rev.00)

**Report No.:** 75949272

**Valid from:** 2021-08-17  
**Valid until:** 2024-02-19

**Date,** 2021-08-17



Christoph Dicks  
Head of Certification/Notified Body

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## 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

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.

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

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.

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

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.

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

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.

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

Design of ECG recorders, ambulatory ECG and NIBP recorders  
and receiving stations, ECG analysers, ECG stress test systems,  
Cardiac Information Management Systems.

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