





## **Product Service**

## **Certificate**

No. Q5 083562 0016 Rev. 02

Holder of Certificate: Spacelabs Healthcare, Inc.

35301 SE Center Street Snogualmie WA 98065

**USA** 

Facility(ies): Spacelabs Healthcare, Inc.

35301 SE Center Street, Snoqualmie WA 98065, USA

See Scope of Certificate.

**Certification Mark:** 



Scope of Certificate: Design, Development, Production and Distribution

of Medical Physiological Monitors, Clinical

Information Systems and Anesthesia Equipment. Contract Manufacturing of Monitoring Equipment used in Cardiology and Anesthesia Delivery

Systems and Ventilators.

ISO 13485:2016 **Applied Standard(s):** 

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

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 083562 0016 Rev. 02

Report No.: 72192618

Valid from: 2023-12-20 Valid until: 2026-12-19

Christoph Dicks Date, 2023-12-13

Head of Certification/Notified Body