Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 083562 0020 Rev. 00

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

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.: 72146843

Valid from: 2019-10-16
Valid until: 2024-05-26

Date, 2019-10-10

Stefan Preiß
Head of Certification/Notified Body

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 083562 0020 Rev. 00

Facility(ies):

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

./.

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

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

TÜV®

By Royal Charter

Supplementary information to AR120 813861

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

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

Date: 18 September 2024

Changes Approved:

Date	Reference Number	Action
18 September 2024	30230573	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Smart Disclosure, Xhibit Central, Xhibit XC4, Xprezzon, Xprezzon Display, BISx Module, Capno Pod, Multigas Module, Qube Compact Monitor, Qube Mini, UV SL Command Module, Capno Module, AriaTele, Xhibit Telemetry Receiver. Original NB Certificate Number: G1 083562 0020 Rev. 00

Inspiring trust for a more resilient world.

18 September 2024

Spacelabs Healthcare, Inc.
35301 SE Center Street
Snoqualmie
Washington
98065
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
G1 083562 0020 Rev. 00	AR120 813861	93/42/EEC Annex II excluding Section 4	30230573	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Smart Disclosure, Xhibit Central, Xhibit XC4, Xprezzon, Xprezzon Display, BISx Module, Capno Pod, Multigas Module, Qube Compact Monitor, Qube Mini, UV SL Command Module, Capno Module, AriaTele, Xhibit Telemetry Receiver. Original NB Certificate Number: G1 083562 0020 Rev. 00

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl