



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 070231 0028 Rev. 00

Manufacturer:

Spacelabs Healthcare Ltd.

Unit B, Foxholes Centre
John Tate Road
Hertford, Hertfordshire SG13 7DT
UNITED KINGDOM

SRN Manufacturer - GB-MF-000001196

Authorized Representative:

MediMark Europe Sarl
11, Rue Emile Zola - BP 2332, 38033 Grenoble Cedex 2,
FRANCE

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 070231 0028 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_070231_0028_Rev._00)

Report No.: 75951160

Valid from: 2024-05-15

Valid until: 2029-05-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-05-15



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zfg.de
 BS-MDR-099



Product Service

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Classification: Class IIa
Device Group: Z12050401 - CARDIOVASCULAR HOLTER ANALYSERS
 Z12050403 - ECG HOLTER RECORDERS
 Z12050404 - BLOOD PRESSURE HOLTER RECORDERS
 Z12059092 - VARIOUS INSTRUMENTS FOR CARDIOLOGY
 AND CARDIAC SURGERY - MEDICAL DEVICE SOFTWARE

Intended Purpose: "-"

The validity of this certificate depends on conditions and/or is limited to the following: "-"

Revision History:

Rev.	Dated	Report	Description
00	2024-05-15	75951160	Initial issuance