By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 818179 R000

Manufacturer: Spacelabs Healthcare Ltd.

Address:
Unit B Foxholes Centre
John Tate Road
Hertford
Hertfordshire
SG13 7DT
United Kingdom

Single Registration Number: GB-MF-000001196

EU Authorised Representative: MediMark Europe Sarl.

Address:
11 rue Emile Zola
38100 Grenoble
France

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-03-28**

Current Issue Date: **2025-03-28**

Starting Validity Date: **2025-03-31**

Expiry Date: **2029-05-14**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cardiovascular Holter Analysers	Class IIa
Blood Pressure Holter Recorders	Class IIa
ECG Holter Recorders	Class IIa
Holter System Instruments for Cardiovascular Parameters – Medical Device Software	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30288196	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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