By Royal Charter

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 818175**

Issued To: **Spacelabs Healthcare Ltd.**
Unit B Foxholes Centre
John Tate Road
Hertford
Hertfordshire
SG13 7DT
United Kingdom

In respect of:

Design, manufacture and final inspection of Cardiovascular Holter Analysers, Blood Pressure Holter Recorders, ECG Holter Recorders and associated Software

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2025-05-26** Date: **2025-05-26** Expiry Date: **2029-05-14**

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Supplementary Information to UKCA 818175

Issued To:

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John Tate Road
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United Kingdom

Device code	Device name	Intended purpose per IFU
Class IIa		
MD 1302	Cardiovascular Holter Analysers	---
MD 1302	Blood Pressure Holter Recorders	---
MD 1302	ECG Holter Recorders	---
MD 1111	Holter System Instruments for Cardiovascular Parameters – Medical Device Software	---

First Issued: **2025-05-26** Date: **2025-05-26** Expiry Date: **2029-05-14**

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UKCA Certificate - Full Quality Assurance System Certificate History

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Date: **2025-05-26**
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Date	Reference Number	Action
Current	30288198	First Issue; Traceable to MDR 818179

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