



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 070231 0018 Rev. 00

Manufacturer:

Spacelabs Healthcare Ltd.

Unit B, Foxholes Centre John Tate Road

Hertford, Hertfordshire SG13 7DT

UNITED KINGDOM

Product Category(ies): ECG Recorders, ECG Analysers,

Ambulatory NIBP Recorders, Cardiac Information Management 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.:

75946292

Valid from:

2020-03-11

Valid until:

2024-05-26

Date,

2020-03-12

Christoph Dicks

Head of Certification/Notified Body