

Certificate of Approval

This is to certify that the Management System of:

Rocket Medical PLC

Also Trading As: Nusurgix

Sedling Road, Washington, NE38 9BZ, United Kingdom

MDSAP Facility Identifier: 54-431-3588

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1

(Excluding Part 1.6) – Full Quality Assurance Procedure

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure [if design controls are excluded from the certification]

Brazil:

RDC ANVISA n. 16/2013

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

United States:

21 CFR 803

21 CFR 806

21 CFR 807 – Subparts A to D



Cliff Muckleroy- Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: LRQ4008742

Original approval:

Effective date: 2019 October 31

MDSAP/ISO 13485 – 2019 October 31

Expiry date: 2022 October 30

Certificate issue number: 10229761

Approval MDSAP – 00022707

The scope of this approval is applicable to:

Design and manufacture of blood collection devices and kits, catheters and catheter insertion kits, CSF sampling devices and kits, CTG electrodes, disposable surgical instruments, electrosurgical instruments, endoscopes, guide wires, irrigation/drainage devices and sets, needles, needle guides, surgical gloves, surgical sponges, syringes, Talc Poudrage and wound dressings, haemorrhoid ligator, non-sterile low vacuum aspiration pumps.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

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