Certificate of Registration of Quality Management System to ISO 13485:2016

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,
☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
Canada - Medical Devices Regulations – Part 1- SOR 98/282
United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Accutron, Inc.
1733 W. Parkside Lane
Phoenix, AZ 85027
USA

Facility ID: F001569

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

Design, manufacture, servicing and distribution of gas machines for analgesia, gas delivery scavenging, tubing circuits, nasal/face masks including ancillary portable manifold systems and central manifold systems. Manufacture and distribution of emergency oxygen equipment.

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.8208 / Rev 1
Certification Granted: 2019/03/27
Effective Date: 2022/03/27
Expiry Date: 2025/03/26

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All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing