

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.
Cantel Medical
1733 W. Parkside Lane
Phoenix, AZ 85027
USA

D-U-N-S: 88302096

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, central manifold systems, emergency oxygen equipment

Approved by: Geraldine Larkin Chief Executive Officer Approved by: Caroline Dore Geraghty Director of Medical Devices / Head of Notified Body

Certificate Number: MP19.8208 / Rev 1 Certification Granted: 2019/03/27

Effective Date: 2019/03/27 Expiry Date: 2022/03/26



