

Certificate GB20/965911

The quality management system of

Armstrong Medical Ltd

SGS

Wattstown Business Park Newbridge Road Coleraine N. Ireland BT52 1BS United Kingdom
Facility number: F004492

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 16/2013 - Good Manufacturing Practices, RDC ANVISA n. 56/2001 - Essential Requirements for Safety and Effectiveness, RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from Effective date 2025-05-13 until Expiry date 2026-04-19 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 2020-05-22

L. Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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MDSAP (ISO 13485:2016)

Issue 6

The design and manufacture of anaesthetic circuits, ventilator circuits, CPAP circuits, resuscitation sets, humidification chambers, breathing filters, respiratory tubing, respiratory facemasks, adaptors, air valves, gas sampling lines, carbon dioxide absorbents, absorbent canister adaptors, nasal interfaces, patient coverings to limit heat loss and associated hypothermia, for the areas of Anaesthesiology, Respiratory, Critical, Neonatal, and Perioperative care.

Japan Jurisdiction:

The design and manufacture of anaesthetic circuits, ventilator circuits, CPAP circuits, resuscitation sets, humidification chambers, breathing filters, respiratory tubing, respiratory facemasks, adaptors, air valves, gas sampling lines, carbon dioxide absorbents, absorbent canister adaptors, nasal interfaces, for the areas of Anaesthesiology, Respiratory, Critical, Neonatal, and Perioperative care



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