Medical Device Full Quality Assurance System Certificate
GB23/00000089

The management system of

Armstrong Medical Ltd

Wattstown Business Park Newbridge Road Coleraine N. Ireland BT52 1BS United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 13 March 2025 until 12 May 2028 and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 17 February 2023

L. Henderson

Authorised by
Lynn Henderson

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Medical Device Full Quality Assurance System Certificate
GB23/00000089, continued

Armstrong Medical Ltd

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 5

Anaesthetic Circuits;
Ventilator Circuits;
CPAP Circuits;
Resuscitation Sets;
Humidification Chambers,
Breathing Filters;
Drug Nebulizers;
Nebulizer Kits;
Catheter Mounts;
Respiratory Tubing;
Respiratory Face Masks;
Adapters; Air Valves;
Water Traps;
Breathing Bags; Port Caps;
Gas Sampling Lines;
Carbon Dioxide Absorbents;
Absorbent Canister Adapters,
Nasal Interfaces,
Gas Flow Driver

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/08349
Previous certificate number: N/A
Change in between this certificate and previous one: Removal of Non sterile Laryngeal Airways from the scope.