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
Anaesthetic Circuits;
Ventilator Circuits;
CPAP Circuits;
Resuscitation Sets;
Humidification Chambers,
Breathing Filters;
Drug Nebulizers;
Nebulizer Kits;
Catheter Mounts;
Respiratory Tubing:

Respiratory Tubing; Respiratory Face Masks; Adapters; Air Valves; Water Traps:

Water Traps; Breathing Bags; Port Caps; Gas Sampling Lines; Carbon Dioxide Absorbents; Absorbent Canister Adapters, Intravenous Administration Sets and Drainage Sets (sterile);

Non sterile Laryngeal Airways. Sterile Pleural Drainage Set, 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: N/A

This certificate is valid from 12 May 2023 until 12 May 2028 and remains valid subject to satisfactory surveillance audits. Issue 3. Certified since 17 February 2023



Authorised by
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Head of Approved Body 0120

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