EC Certificate Full Quality Assurance System: Certificate GB19/964541

The management system of

Armstrong Medical Ltd

Wattstown Business Park, Newbridge Road, Coleraine, N. Ireland, BT52 1BS, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 18 May 2021 until 19 April 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 02 June 1998

Certification is based on reports numbered GB/PC 08349

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Armstrong Medical Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Anaesthetic Circuits;
Ventilator Circuits;
CPAP Circuits;
Resuscitation Sets;
Humidification Chambers,
Breathing Filters;
Drug Nebulizers;
Nebulizer Kits;
Recovery T-Pieces;
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,
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 EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.