

Medical Device Full Quality Assurance System Certificate GB23/00000131

The management system of

Intersurgical Ltd

Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ 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

Certification is based on reports numbered GB/PC/04303

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 16 March 2023 until 26 November 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 16 March 2023

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

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Intersurgical 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]

Sterile and Non-Sterile medical devices for respiratory care,
in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy:

Sterile and Non-Sterile Anaesthetic Breathing Systems
Aerosol and Oxygen Face Masks
Anaesthetic Face Masks
Sterile Endotracheal Tube Introducer and Sterile Airway Stylets
Sterile and Non-Sterile Breathing Systems
Non-Heated Respiratory Bubble Humidifier
Sterile and Non-Sterile Catheter Mounts
Sterile and Non-Sterile Breathing System Connectors
Sterile and Non-Sterile Respiratory Filters
Breathing System Flexible Tubing
High Concentration Oxygen Face Masks
Sterile and Non-Sterile Heat and Moisture Exchangers
Sterile and Non-Sterile HME Filters
Sterile and Non-Sterile Inspiratory Line Humidification Chambers
Sterile I-gel Supraglottic Airways
Sterile Laryngeal Airways
Gas Sampling/Monitoring Respiratory Tubing
Sterile and Non-Sterile Heated Wire Breathing Systems,
Heated Wires and attachments (electrical adaptor leads)
Electrically Powered Moisture Condenser
Nasal Cannulae
Nebulising System Delivery Sets
Suction and Irrigation Oral Care Toothbrush
Oxygen Administration Tubing
Repeated Use Breathing Systems
Breathing Systems Reservoir Bags
Manual Pulmonary Resuscitation Systems
Carbon Dioxide Absorbents
Sterile and Non-Sterile Tracheal Suction Systems
Sterile Endotracheal Tubes
Venturi Valves and Venturi Valve Face Mask Kits



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Wall Humidifier Nebuliser
Breathing System Water Traps
CPAP Bi-level Nasal Masks and NIV Face Masks
Pressure Limiting Valves
Peep Valves
One Way Directional Valves
Infant Nasal CPAP Breathing System
Oxygen Recovery Kits
Endoscopy Molar Bite Block
Carbon Dioxide Cuvette
Class I sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Guedel Airways

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



Intersurgical 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 1
Sites
Intersurgical Ltd. Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ United Kingdom
Intersurgical Ltd. Canister House Molly Millars Bridge RG41 2WY United Kingdom
Intersurgical Ltd. Unit 1 Molly Millars Lane RG41 2QZ United Kingdom
Intersurgical Ltd. Dray House Molly Millars Lane RG41 2PX United Kingdom
Intersurgical Ltd. Brook House Molly Millars Bridge RG41 2WY United Kingdom
UAB Intersurgical Arnionių g. 60 Pabradė LT-18170 Lithuania
UAB Intersurgical Arnionių g. 60A Pabradė LT-18170 Lithuania
UAB Intersurgical Arnionių g. 45 Pabradė LT-18170 Lithuania
UAB Intersurgical Duksto kelias 84A Visaginas LT-31146 Lithuania

