

Certificate GB21/969020

The quality management system of

Intersurgical Ltd.

SGS

Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ United Kingdom

Facility Identification Number: F003832

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

Canada:

Medical Devices Regulations – Part 1 SOR 98/282, Part 1

Japan:

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

Japan PMD Act (as applicable)

United States:

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 2023-11-26 until Expiry date 2026-11-26 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2021-08-04

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

L. Henderson

Authorised by

Lynn Henderson

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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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Intersurgical Ltd.

SGS

MDSAP (ISO 13485:2016)

Design and manufacture of single use and reusable, sterile and non-sterile medical devices for respiratory care in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy, oral care and homecare:

Sterile and Non-sterile Anaesthetic Breathing Systems, Non-sterile Aerosol and Oxygen Face Masks, Non-sterile Anaesthetic Face Masks, Sterile Endotracheal Tube Introducer and Sterile Airway Stylets, Sterile and Non-sterile Breathing Systems, Non-sterile Non-Heated Respiratory Bubble Humidifier, Sterile and Non-sterile Catheter Mounts, Sterile and Non-sterile Breathing System Connectors, Sterile and Non-sterile Respiratory Filters, Non-sterile Breathing System Flexible Tubing, Sterile and Non-sterile Guedel Airways, Non-sterile 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 and Non-sterile Heated Breathing Systems, Heated Wires and attachments (electrical adaptor leads), Sterile Supraglottic Airways, Non-sterile Laryngoscopes Blades and Handles, Non-sterile Video laryngoscope, Sterile Laryngeal Airways, Non-sterile Gas-Sampling / Monitoring Respiratory Tubing, Non-sterile Nasal Cannulae, Non-sterile Nebulising System Delivery Sets, Non-sterile Suction and Irrigation Oral Care Toothbrush, Non-sterile Oxygen Administration Tubing, Non-sterile Repeated Use Breathing Systems, Non-sterile Breathing Systems Reservoir Bags, Non-sterile Manual Pulmonary Resuscitation Systems, Non-sterile Carbon Dioxide Absorbents, Sterile and Non-sterile Tracheal Suction Systems, Sterile Endotracheal Tubes, Non-sterile Tube management devices, Non-sterile Venturi Valves and Venturi Valve Face Mask Kits, Non-sterile Wall Humidifier Nebuliser, Non-sterile Breathing System Water Traps, Non-sterile Electrically Powered Moisture Condenser, Non-sterile CPAP Bi-level Nasal Masks and NIV Face Masks, Non-sterile Pressure Limiting Valves, Non-sterile Peep Valves, Non-sterile One Way Directional Valves, Non-sterile Infant Nasal CPAP breathing system, Non-sterile Oxygen Recovery Kits



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MDSAP (ISO 13485:2016)

Issue 3
Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ United Kingdom
Facility activities: Design and manufacture of sterile and non-sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care and oxygen and aerosol therapy
Campuses
Unit 1 Molly Millars Lane RG41 2QZ United Kingdom
Unit 3 Molly Millars Bridge RG41 2WY United Kingdom
Dray House Molly Millars Lane RG41 2PX United Kingdom
Brook House Molly Millars Bridge RG41 2WY United Kingdom
Additional facilities
UAB Intersurgical (Site 3 campus) Amionių g.60 LT-18170 Pabradė Lithuania Facility identification number: F003849
Facility activities: Manufacture of sterile and non-sterile medical devices, in support of design and manufacture of sterile and non-sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care and oxygen and aerosol therapy.
Campuses
UAB Intersurgical (Site B) Amionių g. 60A Pabradė LT-18170 Lithuania
UAB Intersurgical (Site C and DC) Amionių g. 45 Pabradė LT-18170 Lithuania
Additional facilities
UAB Intersurgical (V-site) Duksto kelias 84A Visaginas LT-31146 Lithuania Facility identification number: F006220
Facility activities: Manufacture of non-sterile medical devices, in support of design and manufacture of sterile and non-sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care and oxygen and aerosol therapy.

