

Certificate GB21/969020

The quality management system of

Intersurgical Ltd.

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

Facility Identification Number: F003832

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

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

Japan:

MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68

Japan PMD Act

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 and devices

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from Effective Date: 12 July 2022 until Expiry Date: 26 November 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 26 September 2023

Issue 2. Certified since 04 August 2021.

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

Authorised by



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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

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



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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
Circuit House Pitronnerie Road Industrial Estate St Peter Port Guernsey GY1 2RL United Kingdom Facility identification number: F004636 Facility activities: Manufacture of single use non-sterile medical devices for respiratory care in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy, oral care and homecare
Additional facilities
UAB Intersurgical (Site 3 campus) Arnionių g.60 LT-18170 Pabradė Lithuania Facility identification number: F003849 Facility activities: 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. Purchasing and supplier management for outsourced medical devices.
Campuses
UAB Intersurgical (Site B) Arnionių g. 60A, Pabradė LT-18170 Lithuania
UAB Intersurgical (Site C and DC) Arnionių 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 single use and reusable non-sterile medical devices for respiratory care in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy, oral care and homecare



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