

The management system of

# Intersurgical Ltd.

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, 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 24 May 2021 until 26 November 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 11 January 1995

Certification is based on reports numbered GB/PC 04303

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Head of Notified Body

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium

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

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# Intersurgical Ltd.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

**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**

**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**

Certificate GB19/964232 continued

# Intersurgical Ltd.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Additional facilities

**Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK**

**Unit 3, Molly Millars Bridge, RG41 2WY, UK**

**Dray House, Molly Millars Lane, RG41 2PX, UK**

**Brook House, Molly Millars Bridge,, RG41 2WY, UK**

**Unit 1, Molly Millars Lane, RG41 2QZ, UK**

**Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port,  
Guernsey, GY1 2RL, UK**

**UAB Intersurgical Arnionių g.60, LT-18170 Pabradė, Lithuania**

**Arnionių g. 60A, Pabradė, LT-18170, Lithuania**

**Arnionių g. 45, Pabradė, LT-18170, Lithuania**

**Duksto kelias 84A, Visaginas, LT-31146, Lithuania**