

EC Certificate Full Quality Assurance System: Certificate GB19/964232

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 26 November 2020 until 26 November 2022  
and remains valid subject to satisfactory surveillance audits.  
Issue 6. Certified since 11 January 1995  
and first certified by SGS Belgium NV since 31 October 2019

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

Certification is based on reports numbered GB/PC 04303

Authorised by



**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 [www.sgs.com](http://www.sgs.com)

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 6

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**



# Intersurgical Ltd.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

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

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.

Additional facilities

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

UAB Intersurgical Arnionių 60, LT-18170 Pabradė, Lithuania