

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

t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 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 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



*[Handwritten signature]*





Certificate GB95/4313

The management system of

## Intersurgical Ltd

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

Brook House, Molly Millars Bridge, Wokingham, Berkshire, RG41 2WY, UK

has been assessed and certified as meeting the requirements of

# ISO 9001:2015

For the following activities

**The design, manufacture, and supply of medical respiratory products.**

This certificate is valid from 08 August 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits.  
Recertification audit due a minimum of 60 days before the expiration date.  
Issue 27. Certified since 11 January 1995



0005

Authorised by

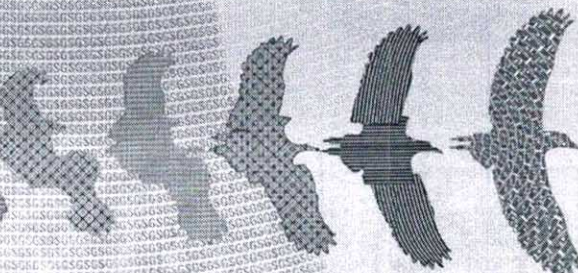
SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

21HC 9001:2015 0421

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Certificate GB06/70658

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The management system of

## Intersurgical Ltd

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

Brook House, Molly Millars Bridge, Wokingham, Berkshire, RG41 2WY, UK

has been assessed and certified as meeting the requirements of

# ISO 14001:2015

For the following activities

**The design, manufacture, and supply of medical respiratory products.**

This certificate is valid from 08 August 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits.  
Recertification audit due a minimum of 60 days before the expiration date.  
Issue 9. Certified since 12 December 2006



0005

Authorised by

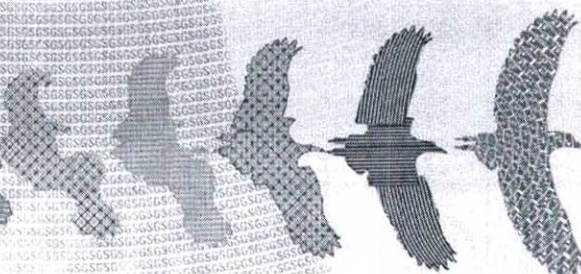
SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
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### Manufacturer's Authorization

Date: 01.08.2022

#### To Whom It May Concern

We Intersurgical Ltd, located at Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom are the registered legal manufacturer of medical device for respiratory support. We have factories located at UAB Intersurgical, Arnoniu, g.60, LT-18170 Pabrade, Lithuania, and Intersurgical Ltd., Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 do hereby declare that

ECHIPAMED PLUS SRL  
str. Valea Trandafirilor 24 "B", of. 2-7  
MD-2001, Chisinau  
Republic of Moldova

is our official distributor and local representative for the complete range of Intersurgical products, , in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, perform installation and after sales service, as well as to perform all the procedures required for the expertise process at state registration (re-registration, etc.) of All Intersurgical Product Range of Medical Devices for Respiratory Support in the Republic Moldova, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2027 and all terms and conditions are as per the Distributor Agreement signed by both parties.

Yours sincerely

INTERSURGICAL LTD.

Crane House  
Molly Millars Lane  
Wokingham, Berks.  
RG41 2RZ

Stephen Williams  
Global Sales Director



## Compact™ extendable anaesthetic breathing systems providing a versatile solution

### Optimum compression

Designed for economy, the unique Compact extendable anaesthetic breathing system can be compressed to almost one fifth of its extended length. Supplied in compressed form increasing the number of systems per box, there can be significant space and cost savings compared with other breathing systems. A standard box of Compact systems could provide a hospital with an extra three weeks supply.

- More Compact systems per box
- Lower storage requirements
- Lower freight volume costs
- Improved disposal

### Low resistance to flow

Designed with a shallow profile resulting in more laminar gas flow and lower resistance to flow. At 60 L/min, resistance to flow of the extended tube is 1.0 cm H<sub>2</sub>O per metre.

### Lightweight system

Lighter than other extendable systems ensuring that the 'pull' on the patient's airway device is kept to a minimum.

### Low compliance

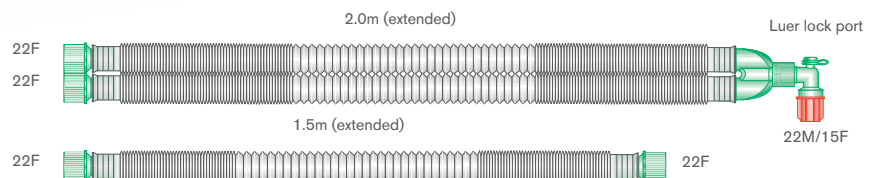
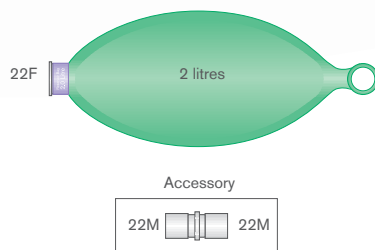
The compliance of the Compact system tube when extended is 4.4ml/kpa per metre of tube, which is less than that required in the ISO 5367:2000 standard.

### Adjustable length

Packed and supplied in the shortest length for simple extension to the length required for clinical use.

### Easy positioning

The nature of the Compact system tube allows for it to be set in any position required. This results in multiple positioning possibilities, ideal for head and neck surgery where the system can be positioned away from the patient, and does not require any additional patient connections.



👁 system illustrated

Code	Description	Box Qty.
2150000	22mm Compact, extendable breathing system with luer elbow, ≥1.5m	70
2151000 (S*)	22mm Compact, extendable breathing system with luer elbow, ≥2.0m	70 (30*)
2152000	22mm Compact, extendable breathing system with 3L bag and limb, ≥2.0m	35
2153000	22mm Compact, extendable breathing system with 3L bag and filter and limb, ≥2.0m	35
👁 2154000 (S*)	22mm Compact, extendable breathing system with 2L bag and limb, ≥2.0m	35 (20*)
2155000	22mm Compact, extendable breathing system with two re-sealable water traps and limb, ≥3.0m	12
2156000	22mm Compact, extendable breathing system with 2L bag and limb, ≥3.0m	25
2157000	22mm Compact, extendable breathing system with 2L bag and limb, ≥3.0m	25
2158000	22mm Compact, extendable breathing system with luer elbow, ≥3.0m	40
1526000	Compact, extension tube ≥2.0m	100

Make an enquiry

🅈 Sterile option available

(S\*) Add an S to the seven digit code number for the sterile version of this product eg. 5000000S (sterile box quantity is shown in brackets).



Contact us

info@intersurgical.com ▪ www.intersurgical.com