

UAB Intersurgical

Amioniu g. 60, Pabrade, LT-10170, Lithuania

T: +370 387 66611 F: +370 387 66622

info@intersurgical.lt www.intersurgical.lt

2018-07-23

No. SI18-279

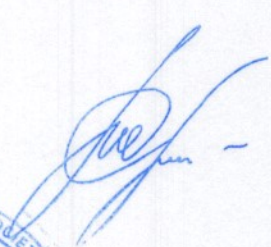
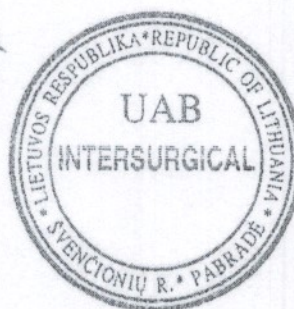
To whom it may concern

We are pleased to confirm that *Echipamed - Plus S.R.L.* is an official distributor for all Intersurgical product range in Moldova.

Should you have any questions, you may contact me at +370 387 66612.

Sincerely,

Meilutė Milišauskienė  
European sales manager  
Intersurgical UAB



Sales administrator Renata Pacar, phone: (+00)370 38735113, e-mail: [R.Pacar@intersurgical.com](mailto:R.Pacar@intersurgical.com)



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 28 August 2015 until 26 November 2019  
and remains valid subject to satisfactory surveillance audits.

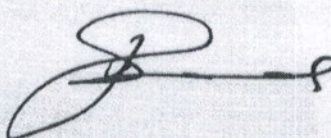
Re certification audit due before 02 October 2017  
Issue 26. Certified since 11 January 1995

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



**SGS United Kingdom Ltd, Notified Body 0120**

SGS United Kingdom Ltd Systems & Services Certification  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Page 1 of 2





# Intersurgical Ltd

## Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 26

Detailed scope

### Non sterile medical devices:

- For Airway Management: connectors, breathing filters, heat and moisture exchangers, heat and moisture exchanging filters.
- For Anaesthesia: Breathing systems, carbon dioxide absorbents, catheter mounts, connectors, breathing filters, heat and moisture exchanging filters, masks and attachments, monitoring and pressure lines and filters, reservoir bags, resuscitation systems and masks, tubing and attachments, valves - directional, positive end expiratory pressure, pressure limiting, and exhalation.
  - For Critical Care: breathing filters, breathing systems, catheter mounts, connectors, heat and moisture exchangers, heat and moisture exchanging filters, heated wire breathing systems and attachments, humidification chambers, lung volume recruitment systems, masks and attachments, monitoring and pressure lines and filters, oral care treatment - suction and irrigation toothbrushes and kits, resuscitation systems and masks, suction devices - tubing and wands, tubing and attachments, valves - directional, positive end expiratory pressure, pressure limiting and exhalation, venturi valves for oxygen therapy, electrically powered moisture condenser for breathing systems
- For Oxygen and Aerosol Therapy: connectors, masks and attachments, nasal cannulae, nebulisers and nebuliser systems, tubing and attachments, water traps.

### Sterile medical devices:

- For Airway Management: airways, bougies and stylets, connectors, breathing filters, heat and moisture exchangers, heat and moisture exchanging filters.
  - For Anaesthesia: breathing filters, breathing systems, catheter mounts, connectors, heat and moisture exchanging filters, masks and attachments.
  - For Critical Care: breathing filters, breathing systems, catheter mounts, connectors, endotracheal closed suction systems, heat and moisture exchangers, heat and moisture exchanging filters, heated wire breathing systems and attachments, humidification chambers, suction devices - tubing, water for oral rinsing.
- For Oxygen and Aerosol Therapy: connectors.

Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

- For Airway Management: 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

UAB „INTERSURGICAL“, Arnioniu g. 60/28 - 1, LT-18170 Pabradė, Lithuania

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





# SGS

Certificate GB95/6635

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

### ISO 13485:2003 EN ISO 13485:2012

For the following activities

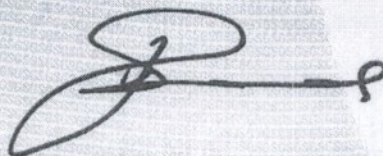
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 27 November 2017 until 31 March 2019  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019  
Issue 26. Certified since 11 January 1995

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

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

SGS 13485-2 0614 M2

Page 1 of 2



0005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



# SGS

Certificate GB95/6635, continued

## Intersurgical Ltd.

### ISO 13485:2003 EN ISO 13485:2012



Issue 26

Detailed scope

**Design and sterile and non-sterile medical devices for respiratory care,  
in the areas of airway management, anaesthesia, critical care,  
and oxygen and aerosol therapy.**

Additional facilities

**UAB „INTERSURGICAL“  
Arnionių g. 60/28 - 1, LT-18170 Pabradė, Lithuania**

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



0005