

UAB Intersurgical
Amioniu g. 60, Pabrade, LT-18170, Lithuania
T: +370 387 66611 F: +370 387 66622
info@intersurgical.lt www.intersurgical.lt

2018-07-23
No. S118-279

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: RP@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.

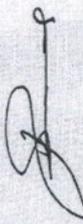
This certificate is valid from 28 August 2015 until 26 November 2019 and remains valid subject to satisfactory surveillance audits.

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

Certification is based on reports numbered GBPC-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
2028 Wolfe Parkway, Wokingham, Berkshire, RG41 2RZ, UK
t +44 (0)1834 522817 f +44 (0)1834 522197 www.sgs.com

SGS CE 02 0315 MZ

Page 1 of 2



This document is issued by the Company subject to its Terms of Conditions of Certification. Services are available at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the fact that the validity of this certificate and the jurisdiction of the Notified Body is subject to the conditions of the contract of certification. The certificate holder is responsible for the maintenance of the certificate. Any unauthorised alteration, forgery or falsification of the content or appearance of this document is prohibited and may be prosecuted to the full extent of the law.

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

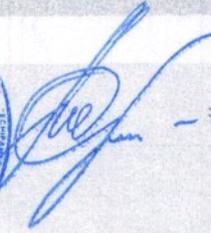
- For Airway Management: guedel airways.

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“, Amioniu g. 60/28 - 1, LT-18170 Pabradė, Lithuania
Intersurgical Limited, Circuit House, Pitronnerie Road Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

Page 2 of 2



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
Rosemore Business Park, Epsom Road, Chesham, Bucks, UK
1+44 (0)151 350-6956 1+44 (0)151 352-6900 www.sgs.com

SGS 14485-2 0614 MZ

Page 1 of 2



SGS



The document is issued by the Client's subject to the Client's Conditions of Certification. Services available at www.sgs.com and are conditional upon the Client's compliance with the Client's Conditions of Certification. The authority of this document may be verified at www.sgs.com. Any unauthorised 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“
Armioniu g. 60/28 - 1, LT-18170 Pabradė, Lithuania

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



0005

The document is issued by the Client's subject to the Client's Conditions of Certification. Services available at www.sgs.com and are conditional upon the Client's compliance with the Client's Conditions of Certification. The authority of this document may be verified at www.sgs.com. Any unauthorised 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.

Page 2 of 2

SGS

Certificate GB95/4313



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 9001:2008

For the following activities

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

This certificate is valid from 27 November 2017 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 15 September 2018
Issue 23. Certified since 11 January 1995

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



0005

Authorised by

SGS (United Kingdom) Ltd
Rosemore Business Park, Eillewore Road, Chesham, Ch65 3EN, UK
t +44 (0)151 350-6865 f +44 (0)151 350-6900 www.sgs.com

IAF SGS 9001 2008 0117 142

Page 1 of 2



SGS



The document is issued by the Competent Authority in the Country of origin of the Certificate. Services provided by www.sgs.com/uk, and associated services, are available to the holders of facility, accreditation and certification certificates issued by SGS. The information in this document is provided for informational purposes only and does not constitute a contract. Any unauthorised alteration, copying or fabrication of the content or appearance of the document is subject to legal action. The information in this document is subject to change without notice.

SGS

Certificate GB95/4313, continued

Intersurgical Ltd.

ISO 9001:2008

Issue 23

Detailed scope

Design and manufacture 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“
Armoniti g. 60/28 -1, LT-18170 Pabrade, Lithuania
Intersurgical Ltd.
Circuit House, Pitromerie Road, Industrial Estate,
St Peter Port, Guernsey, GY1 2RL, UK



0005



The document is issued by the Competent Authority in the Country of origin of the Certificate. Services provided by www.sgs.com/uk, and associated services, are available to the holders of facility, accreditation and certification certificates issued by SGS. The information in this document is provided for informational purposes only and does not constitute a contract. Any unauthorised alteration, copying or fabrication of the content or appearance of the document is subject to legal action. The information in this document is subject to change without notice.

Page 2 of 2