

EC Certificate Full Quality Assurance System: GB957676.00, continued

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 Critical Care: breathing filters, breathing systems, catheter monitors, connectors, heat and moisture exchangers, heat and moisture exchanging liners, 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

and fillers, 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 expiratory pressure release, manual ventilation devices, manual respiration 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 attachers, water traps.

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

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 attachments.

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- For Oxygen and Aerosol Therapy: connectors.

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

For Alignment Management: avoid alignment

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SGS

Certificate GB95/6635



The management system of

Intersurgical Ltd.

Crane House, Moley 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
Rosemoor Business Park, Epsom Road, Chesham, Bucks HP8 5EN, UK
t +44 (0)151 350-6995 f +44 (0)151 352-6900 www.sgs.com

SGS 13485-2 0614 M2

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The scope of this certificate is limited to the activities of the client. The client is responsible for ensuring that the scope of the certificate is correctly stated and that the certificate is used only for the purposes for which it was issued. The client is also responsible for ensuring that the certificate is not used for any other purpose.

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“
Amioniu g. 60/28 - 1, LT-18170 Pabradė, Lithuania

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



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The document is issued by the Client subject to the Client's Conditions of Certification. The Client is responsible for ensuring that the scope of the certificate is correctly stated and that the certificate is used only for the purposes for which it was issued. The client is also responsible for ensuring that the certificate is not used for any other purpose.

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SGS

Certificate GB95/4313



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.



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Authorized by

[Signature]

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of the law.

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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“
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