INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

ISO 9001:2008 ISO 13485:2003

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

Digitally signed by Iurchevici Valeriu
Date: 2019.11.29 18:50:52 EET
Reason: MoldSign Signature
Location: Moldova

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

LIETUVOS RESPUBLIKA • REPUBLIC OF LITHUANIA • UAB INTERSURGICAL • ŠVENČIONIŲ R. • PABRADĖ

REPUBLICA MOLDOVA mun. CHIȘINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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

EC Certificate Full Quality Assurance System: GB95/7676

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 04 October 2018 until 26 November 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 October 2020
Issue 28. 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
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

Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 28

Detailed scope

Sterile and non-sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care, and oxygen and aerosol therapy :
• Sterile & non-sterile Anaesthetic Breathing Systems
• Non-sterile Aerosol and Oxygen Masks
• Non-sterile Anaesthetic Masks • Sterile Bougies and Stylets
• Sterile & non-sterile Breathing Systems
• Non-sterile Bubble Humidifier • Non-sterile Caps
• Sterile, non-sterile Catheter Mounts • Sterile, non-sterile Connectors
• Sterile & non-sterile Respiratory Filters
• Non-sterile Flextube Flexible Tubing
• Non-sterile High Concentration Oxygen Masks
• Sterile & non-sterile Heat and Moisture Exchangers
• Sterile & non-sterile HME Filters
• Sterile & non-sterile Humidification Chambers
• Sterile & non-sterile Heated Wire Breathing Systems, Heated Wires & attachments (electrical adaptor leads)
• Sterile & non-sterile I-gel Supraglottic Airways • Sterile Laryngeal Mask Airways
• Non-sterile Monitoring Line Filters • Non-sterile Monitoring Lines
• Non-sterile Nasal Cannulae • Non-sterile Nebulisers
• Non-sterile suction and irrigation toothbrush
• Non-sterile Oxygen Lines • Non-sterile Repeated Use Breathing Systems
• Non-sterile & sterile Reservoir Bags • Non-sterile Rescuer Mask
• Non-sterile manual Resuscitation Systems
• Non-sterile CO2 absorbents and anaesthesia systems containing absorbents
• Non-sterile Suction Tubes & wands
• Sterile & non-sterile Suction System • Sterile Endotracheal Tubes
• Non-sterile Venturi Valves • Non-sterile Wall Nebuliser
• Non-sterile Water Traps • Non-sterile CPAP and NIV Masks
• Non-sterile Pressure Limiting Valves • Non-sterile Peep Valves
• Non-sterile Exhalation Valves • Non-sterile One Way Directional Valves
• Non-sterile nFlow Infant Nasal CPAP device
• Non-sterile Oxygen Recovery Kits
• Non-sterile electrically powered moisture condenser for breathing systems

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

UAB „INTERSURGICAL" Arnionių 60, LT-18170 Pabradė, Lithuania

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

Certificate GB95/4313

The management system of

Intersurgical Ltd

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

Unit 1, The Business Centre, Molly Millars Lane, Wokingham, Berkshire, 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 2018 until 08 August 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 July 2021
Issue 26. Certified since 11 January 1995

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

HC SGS 9001 2015 0118

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 13485:2016
EN ISO 13485:2016

For the following activities

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

This certificate is valid from 19 March 2019 until 26 November 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 November 2019
Issue 29. 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

HC SGS 13485 2016 0118 M2

Intersurgical Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 29

Detailed scope

Design and manufacture of 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

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

UAB Intersurgical
Arnionių g. 60, LT-18170 Pabradė, Lithuania

UKAS MANAGEMENT SYSTEMS
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