

Quality, innovation and choice



UAB Intereurgical 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. 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: RP@intersurgical.com

UK • Ireland • France • Germany • Spain • Portugal • Italy • Benelux • Sweden • Denmark • Lithuania • Russia • Czech Republic Turkey • South Africa • China • Japan • Taiwan • Philippines • USA • Canada • Colombia • Australia UAB Intersurgical Registered in Lithuania, code 111502432, VAT code LT115024314



EC Certificate Full Quality Assurance System: Certificate GB19/964232

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 31 October 2019 until 26 November 2022 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 11 January 1995 and first approved by SGS Belgium on 31 October 2019.

> This is a multi-site certification. Additional site details are listed on subsequent pages

> > Certification is based on reports numbered GB/PC 04303

Authorised by

SO

Pieter Wetering Certification Manage

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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SGSS



Certificate GB19/964232 continued

Intersurgical Ltd. Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

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 Non-sterile Aerosol and Oxygen Masks • Non-sterile Anaesthetic Masks Sterile Bougies and Stylets
Sterile and non-sterile Breathing Systems Non-sterile Bubble Humidifier
Non-sterile Caps Sterile and non-sterile Catheter Mounts Sterile and non-sterile Connectors Sterile and non-sterile Respiratory Filters Non-sterile Flextube Flexible Tubing Non-sterile High Concentration Oxygen Masks
Sterile and non-sterile HME Filters Sterile and non-sterile Humidification Chambers
Sterile I-gel Supraglottic Airways Sterile Laryngeal Mask Airways
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 Reservoir Bags Non-sterile Manual Resuscitation Systems Non-sterile CO2 Asorbents and Anaesthesia Systems containing Absorbents Non-sterile Suction Tubes and Wands Sterile and 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
Non-sterile Molar Bite Block Non-sterile Mainstream Monitoring (CO2 Cuvette)

Class I sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions • Sterile Guedel Airways

Additional facilities

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

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

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CERTIE

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 PCCOCNITION ARRANGEBEL

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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.sqs.com

HC 5GS 9001 2015 01 18

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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 13485:2016 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 t +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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SGSSG







Certificate GB95/6635, continued



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 alrway management, anaesthesia, critical care and oxygen and aerosol therapy.

Additional facilities

Page 2 of 2

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

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



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