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

Digitally signed by Iurchevici Valeriu
Date: 2022.03.11 17:34:33 EET
Reason: MoldSign Signature
Location: Moldova

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

Pieter Wetenings
Certification Manager

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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

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

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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

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 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 27. Certified since 11 January 1995

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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21HC 9001 2015 0421

Certificate GB06/70658

The management system of

Intersurgical Ltd

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

Brook House, Molly Millars Bridge, Wokingham, Berkshire, RG41 2WY, UK

has been assessed and certified as meeting the requirements of

ISO 14001:2015

For the following activities

The design, manufacture, and supply of medical respiratory products.

This certificate is valid from 08 August 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 9. Certified since 12 December 2006

Authorised by

SGS United Kingdom Ltd
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21HC 14001 2015 0421

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

ISO 9001: 2008 ISO 13485: 2003

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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

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