

Intersurgical Ltd.

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

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
Aerosol and Oxygen Face Masks
Anaesthetic Face Masks
Sterile Endotracheal Tube Introducer and Sterile Airway Stylets
Sterile and Non-Sterile Breathing Systems
Non-Heated Respiratory Bubble Humidifier
Sterile and Non-Sterile Catheter Mounts
Sterile and Non-Sterile Breathing System Connectors
Sterile and Non-Sterile Respiratory Filters
Breathing System Flexible Tubing
High Concentration Oxygen Face Masks
Sterile and Non-Sterile Heat and Moisture Exchangers
Sterile and Non-Sterile HME Filters
Sterile and Non-Sterile Inspiratory Line Humidification Chambers
Sterile I-gel Supraglottic Airways
Sterile Laryngeal Airways
Gas Sampling/Monitoring Respiratory Tubing
Sterile and Non-Sterile Heated Wire Breathing Systems,
Heated Wires and attachments (electrical adaptor leads)
Electrically Powered Moisture Condenser
Nasal Cannulae**

Authorised by



Global Medical Devices Certification Manager

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

LPMD5105 – Corrigendum to Certificate

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SGS Belgium NV

Certification and Business Enhancement Maatschappelijke Zetel/Siège Social:
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www.be.sgs.com

Member of the SGS Group

RPR Antwerp VAT – BE 0404.882.750 Citibank BE87 5701 3412 5594

Nebulising System Delivery Sets
Suction and Irrigation Oral Care Toothbrush
Oxygen Administration Tubing
Repeated Use Breathing Systems
Breathing Systems Reservoir Bags
Manual Pulmonary Resuscitation Systems
Carbon Dioxide Absorbents
Sterile and Non-Sterile Tracheal Suction Systems
Sterile Endotracheal Tubes
Venturi Valves and Venturi Valve Face Mask Kits
Wall Humidifier Nebuliser
Breathing System Water Traps
CPAP Bi-level Nasal Masks and NIV Face Masks
Pressure Limiting Valves
Peep Valves
One Way Directional Valves
Infant Nasal CPAP Breathing System
Oxygen Recovery Kits
Endoscopy Molar Bite Block
Carbon Dioxide Cuvette
Class I sterile: Sterility aspects only - Restricted to the aspects of
manufacture
concerned with securing and maintaining sterile conditions:
Sterile Guedel Airways

This corrigendum is only valid together with accompanying 93/42/EEC certificate
issue 8

<u>Correction Date</u>	<u>Correction</u>
Change approved by SGS on 11 January 2022	The client is removing one of their additional sites : Unit 3 Mollay Millars Bridge, RG41 2WY

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 24 May 2021 until 26 November 2023
and remains valid subject to satisfactory surveillance audits.

Issue 8. 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

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

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

Aerosol and Oxygen Face Masks

Anaesthetic Face Masks

Sterile Endotracheal Tube Introducer and Sterile Airway Stylets

Sterile and Non-Sterile Breathing Systems

Non-Heated Respiratory Bubble Humidifier

Sterile and Non-Sterile Catheter Mounts

Sterile and Non-Sterile Breathing System Connectors

Sterile and Non-Sterile Respiratory Filters

Breathing System Flexible Tubing

High Concentration Oxygen Face Masks

Sterile and Non-Sterile Heat and Moisture Exchangers

Sterile and Non-Sterile HME Filters

Sterile and Non-Sterile Inspiratory Line Humidification Chambers

Sterile I-gel Supraglottic Airways

Sterile Laryngeal Airways

Gas Sampling/Monitoring Respiratory Tubing

Sterile and Non-Sterile Heated Wire Breathing Systems,

Heated Wires and attachments (electrical adaptor leads)

Electrically Powered Moisture Condenser, Nasal Cannulae

Nebulising System Delivery Sets

Suction and Irrigation Oral Care Toothbrush

Oxygen Administration Tubing

Repeated Use Breathing Systems

Breathing Systems Reservoir Bags

Manual Pulmonary Resuscitation Systems

Carbon Dioxide Absorbents

Sterile and Non-Sterile Tracheal Suction Systems

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Endoscopy Molar Bite Block

Carbon Dioxide Cuvette

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Sterile Guedel Airways

Certificate GB19/964232 continued

Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Additional facilities

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

Unit 3, Molly Millars Bridge, RG41 2WY, UK

Dray House, Molly Millars Lane, RG41 2PX, UK

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

Unit 1, Molly Millars Lane, RG41 2QZ, UK

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

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

Arnionių g. 60A, Pabradė, LT-18170, Lithuania

Arnionių g. 45, Pabradė, LT-18170, Lithuania

Duksto kelias 84A, Visaginas, LT-31146, Lithuania