



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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LPM05007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 3



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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**
- Sterile Endotracheal Tubes**
- Venturi Valves and Venturi Valve Face Mask Kits**
- Wall Humidifier Nebulliser**
- 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

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





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



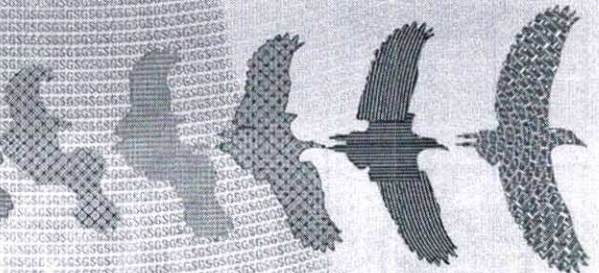
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21HC 9001 2015 0421

Page 1 of 1



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Certificate GB06770658



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



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21HC 14001:2015_0421

Page 1 of 1



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Manufacturer's Authorization

Date: 01.08.2022

To Whom It May Concern

We Intersurgical Ltd, located at Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom are the registered legal manufacturer of medical device for respiratory support. We have factories located at UAB Intersurgical, Arnoniu, g.60, LT-18170 Pabrade, Lithuania, and Intersurgical Ltd., Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 do hereby declare that

ECHIPAMED PLUS SRL
str. Valea Trandafirilor 24 "B", of. 2-7
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for the complete range of Intersurgical products, , in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, perform installation and after sales service, as well as to perform all the procedures required for the expertise process at state registration (re-registration, etc.) of All Intersurgical Product Range of Medical Devices for Respiratory Support in the Republic Moldova, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2027 and all terms and conditions are as per the Distributor Agreement signed by both parties.

Yours sincerely

INTERSURGICAL LTD.
Crane House
Molly Millars Lane
Wokingham, Berks.
RG41 2RZ

Stephen Williams
Global Sales Director



Air-Guard™

For use in respiratory systems and oxygen concentrators

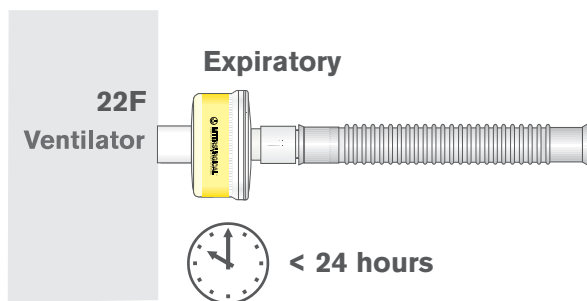
The Intersurgical Air-Guard is a hydrophobic pleated mechanical filter for the protection of oxygen concentrators and other respiratory equipment.

Providing an excellent level (>99.9999%) of protection against bacterial and viral challenges, the Air-Guard's product performance has been tested, validated and verified at independent microbiological laboratories.

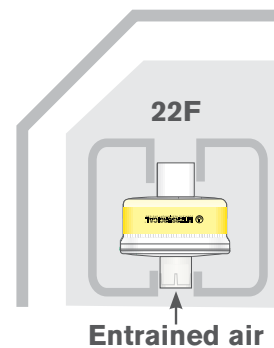
The Air Guard pleated mechanical filter is validated for 24-hours use but this can be extended when used in non-humidified gas flow. The product can be used for extended periods of time for the protection of oxygen concentrators, upon the discretion of the clinician.

Please note: This product is contraindicated for use at the patient connection end of the breathing system.

Respiratory system protection



Oxygen concentrator protection



Air-Guard Clear	
Code	1790000 (S*)
Box Qty.	50 (40*)
Filtration efficiency	>99.9999%
Resistance to flow at 30L/min	0.9cm H ₂ O
Resistance to flow at 60L/min	1.9cm H ₂ O
Compressible volume	120ml
Weight	56g
Connectors	22F-22M/15F
Minimum Tidal Volume	>360ml

[Make an enquiry](#)



 Sterile option available

(S*) Add an S to the seven digit code number for the sterile version of this product eg. 5000000S (sterile box quantity is shown in brackets).