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 25 April 2018 until 26 November 2022
And remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 October 2020
Issue 27. 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

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SGS CE 02 0315 M2

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Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 27

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

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

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