

UAB Intersurgical
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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



Sales administrator Renata Pacar, phone: (+00)370 38735113, e-mail: RP@intersurgical.com

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 GSPFC 04303

Authorised by

Peter Wierings
Certification Manager
SGS Belgium NV, Notified Body 1639

SGS House Noordlaan 87 2000 Antwerp Belgium
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UN050207 Certificate CE1639 Annex 1-4, EN rev 02

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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 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 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

Additional facilities
UAB Intersurgical, Amioniu 80, LT-18170 Pabradė, Lithuania
Circuit House, Pironnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

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