



ECHIPAMED

P L U S

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

tel. +373 (22) 234 349, 234 225; fax +373 (22) 234 225

e-mail: office@echipamed.com, info@echipamed.com

Nr. F/N

din 17.09.2023

*Către Agenția Medicamentului
și Dispozitivelor Medicale*

Notificare

**pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale**

Solicitantul **„Echipamed-Plus” SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr	Nr. Cat.	Denumire	Denumire comercială	Model
1	1790000	Microbial mechanical filter, protection of oxygen concentrators and respiratory equipment	Intersurgical	Air-Guard Clear

Se anexează următoarele acte:

1. Declarații de conformitate CE.
2. Declarații de la producător privind desemnarea reprezentantului.
3. Declarație pe proprie răspundere.

Data 17.09.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	



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*Către Agenția Medicamentului
și Dispozitivelor Medicale*

Declarație pe proprie răspundere

Solicitant: **„Echipamed-Plus” SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificare dispozitivului medical:

Nr	Nr. Cat.	Denumire	Denumire comercială	Model
1	1790000	Microbial mechanical filter, protection of oxygen concentrators and respiratory equipment	Intersurgical	Air-Guard Clear

Sunt autentice și corespund realității.

Director Valeriu Iurchevici

Semnătura _____

Nr.	Numărul de catalog (referință)	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)	Modelul	Cod GMDN	Clasa dispozitivului
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1	1790000	Microbial mechanical filter, protection of oxygen concentrators and respiratory equipment	Intersurgical	Air-Guard Clear	60837	Ila
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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

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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

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



[Handwritten signature]



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



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Authorised by

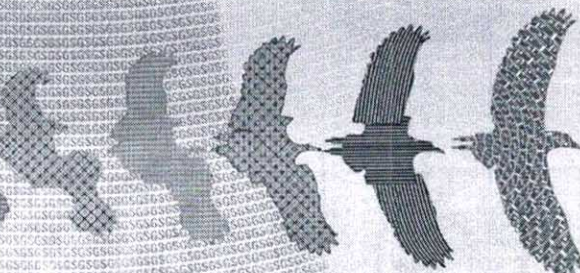
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 9001:2015 0421

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Certificate GB06/70658

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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



0005

Authorised by

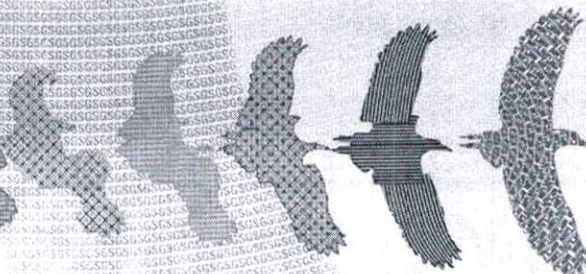
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 14001:2015_0421

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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



EC Declaration of Conformity

We, Intersurgical Ltd (address: Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom) as manufacturer, hereby declare under the sole responsibility of that the below mentioned devices comply with European Medical Devices Directive 93/42/EEC with all amendments and transposing legislation.

Authorised Representative in the European Economic Area (EEA):
UAB Intersurgical (address: Arnioniu g. 60, Pabradė, LT-18170, Lithuania)

Filters

These are class IIa devices in accordance with rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)

GMDN code – 60837, 63171, 63459, 61097, 60506

Essential requirements checklist is on IQR139.

Internally manufactured components master data is on EFACS (Parts Master) and design drawings are on IQR69 (Product and Mould Drawing List).

Internally manufactured finished products master data, production drawings and Master Product Formulae are on EFACS (Master Product Formula, Parts Master) and IQR69 (Product and Mould Drawing List).

Externally manufactured materials, components, design drawings and products are on EFACS (Parts Master), IQR98 (Incoming Product Specification) and IQR69 (Product and Mould Drawing List).

Instructions for use, pack inserts and labels are as detailed on EFACS (Master Product Formula) and IQR107 (Index of Controlled Artworks).

Label content is on EFACS (Master Product Formula) and Labels Printing System.

Product realisation processes are referenced in IQM section 7.1

Product Codes

As listed in EFACS MPF Details under group DCFILTER.DOC.

This range is subject to the procedure set out in Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC, under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87-2030, Antwerpen, Belgium

EC Certificate Full Quality Assurance System GB19/964232 has been issued for the management system of Intersurgical Ltd, which has been assessed and certified according to the requirements of Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC.



Ivan Seniut
Group Quality and Regulatory Affairs Director
Duly authorised for and on behalf of Intersurgical Ltd
Crane House, Molly Millars Lane, Wokingham,
Berkshire, RG41 2RZ, United Kingdom

Issue 21
Valid from 7 April 2022
DCFILTER.DOC

Appendix for Declaration of Conformity Group: DCFILTER.DOC

Product Codes:

1344000S	1344002S	1344007S	1344009S	1344010S
1344011S	1344012S	1344131	1344351S	1344711S
1544000	1544007	1544011	1544012	1544197
1544351	1545000	1545020	1644000	1644007
1644011	1644012	1644035	1644137	1690000
1690000S	1690001	1690003	1690007	1691000
1691001	1691002	1691003	1691004	1691005
1691006	1691007	1691008	1691009	1691010
1691011	1691012	1691013	1691014	1691015
1691016	1691017	1691020	1691050	1691051
1691052	1691053	1691063	1691065	1691090
1691091	1691092	1691093	1691094	1744000S
1744002S	1744011S	1744580S	1745000	1745011
1745012	1745015	1745136	1745197	1745351
1745352	1745711	1788000	1790000	1790000S
1790007	1944000	1944003	1944003S	1944007S
1944011	1944700	2715000	4708000	5361000