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 şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr	Nr. Cat.	Denumire	Denumire comercială	Model
1	8080010	Stilet de intubare	Intersurgical	InterForm intubating stylet, 10FR, 3.3mm, 340mm
2	8080014	Stilet de intubare	Intersurgical	InterForm intubating stylet, 14FR, 4.7mm, 340mm
3	5469000	Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal	Intersurgical	OptiLube, sachets of lubricant, 5g

Se anexează următoarele acte:

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

Digitally signed by Iurchevici Valeriu
Date: 2023.09.17 15:47:00 EEST
Reason: MoldSign Signature
Location: Moldova

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

Nr. F/N
din 17.09.2023

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, cunoscînd prevederile art. **352[1]**, 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	8080010	Stilet de intubare	Intersurgical	InterForm intubating stylet, 10FR, 3.3mm, 340mm
2	8080014	Stilet de intubare	Intersurgical	InterForm intubating stylet, 14FR, 4.7mm, 340mm
3	5469000	Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal	Intersurgical	OptiLube, sachets of lubricant, 5g

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
1	8080010	Stilet de intubare	Intersurgical	InterForm intubating stylet, 10FR, 3.3mm, 340mm	37469	IIa
2	8080014	Stilet de intubare	Intersurgical	InterForm intubating stylet, 14FR, 4.7mm, 340mm	37469	IIa
3	5469000	Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal	Intersurgical	OptiLube, sachets of lubricant, 5g	33587	IIa

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
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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

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

Certificate GB06/70658

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

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

INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

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, Guermsey, 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

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

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)

Resuscitation Systems
These are class IIA medical devices, in accordance with rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)
GMDN code – 36086, 46823, 46634
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 DCRESUS.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 18
Valid from 1 January 2021
DCRESUS.DOC

Intersurgical Limited Registered in England No. 1488409
Directors S. K. Williams • H. Bellm • K. Jacob • D. Williams • M. Hinton

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

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.

I-gel Supraglottic Airways
These are class IIA medical devices, in accordance with rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)
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 DCIGEL.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 10
Valid from 7 February 2020
DCIGEL.DOC

Intersurgical EC Declaration of Conformity Groups (DC Group) Report
Showing product codes covered by each Declaration of Conformity

September, 2019

EC Declaration of Conformity Group: DCIGEL.DOC **DOC 19**

Products:

8201000	8202000	8203000	8204000	8205000
I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1.0, NEONATE, 2-5KG	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.0, SMALL PAEDIATRIC	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 3, SMALL ADULT, 30-60KG	I-GEL, MEDIUM ADULT, SUPRAGLOTTIC AIRWAY, SIZE 4 (50-90KG)	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 5, LARGE ADULT, 90+KG
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL
8215000	8225000	8604000	8703000	8703030
I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1.5, INFANT, 5-12KG	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.5	I-GEL PLUS,MEDIUM ADULT,SUPRAGLOTTIC AIRWAY,SIZE 4 (50-90KG)	I-GEL O2 RESUS PACK - SIZE 3	I-GEL O2 RESUS PACK, SMALL ADULT, SIZE 3
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL
8704000	8704030	8705000	8705030	8800000
I-GEL O2 RESUS PACK - SIZE 4	I-GEL O2 RESUS PACK, SMALL ADULT, SIZE 3	I-GEL O2 RESUS PACK - SIZE 5	I-GEL O2 RESUS PACK, LARGE ADULT, SIZE 5	AIRWAY SUPPORT STRAP
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL