



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	8203000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.3
2	8204000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.4
3	8205000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.5
4	5469000	Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal	Intersurgical	OptiLube, sachets of lubricant, 5g
5	2732000	Linie de preluare a probei de gaz la CO2	Intersurgical	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock, 2,45cm
6	2715000	Filtru pentru linia de preluare a probei de gaz la CO3	Intersurgical	Hydrophobic filter for the monitor connection to protect the monitor,
7	2154000	Seturi de circuite respiratorii	Intersurgical	Compact™ extendable anaesthetic breathing systems, 22 mm, adult
8	4538850	Seturi de circuite respiratorii	Intersurgical	Flextube dual heated wire breathing system, 10 mm, paediatric
9	4504850	Seturi de circuite respiratorii	Intersurgical	Flextube single heated wire breathing system, 15 mm, paediatric
10	2811000	Accesorii pentru circuite respiratorii	Intersurgical	Reservoir bag, 1L with anti occlusion cage mount, 15F neck

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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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, 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	8203000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.3
2	8204000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.4
3	8205000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.5
4	5469000	Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal	Intersurgical	OptiLube, sachets of lubricant, 5g
5	2732000	Linie de preluare a probei de gaz la CO2	Intersurgical	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock, 2,45cm
6	2715000	Filtru pentru linia de preluare a probei de gaz la CO3	Intersurgical	Hydrophobic filter for the monitor connection to protect the monitor,
7	2154000	Seturi de circuite respiratorii	Intersurgical	Compact™ extendable anaesthetic breathing systems, 22 mm, adult
8	4538850	Seturi de circuite respiratorii	Intersurgical	Flextube dual heated wire breathing system, 10 mm, paediatric
9	4504850	Seturi de circuite respiratorii	Intersurgical	Flextube single heated wire breathing system, 15 mm , paediatric
10	2811000	Accesorii pentru circuite respiratorii	Intersurgical	Reservoir bag, 1L with anti occlusion cage mount, 15F neck

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	8203000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.3	45036	Ila
2	8204000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.4	45036	Ila
3	8205000	Masca laringiană supraglotică	Intersurgical	i-gel®, supraglottic airway nr.5	45036	Ila
		Gel pentru tuburi endotraheale, măști laringiene și dispozitive de acces oronazofaringeal				
4	5469000	Linie de preluare a probei de gaz la CO2	Intersurgical	OptiLube, sachets of lubricant, 5g Respiratory gas monitoring line, 1.2mm	33587	Ila
5	2732000	Filtru pentru linia de preluare a probei de gaz la CO3	Intersurgical	ID, male luer lock/male luer lock, Hydrophobic filter for the monitor connection to protect the monitor,	61832	Ila
6	2715000		Intersurgical	Compact™ extendable anaesthetic breathing systems, 22 mm, adult	63459	Ila
7	2154000	Seturi de circuite respiratorii	Intersurgical	Flextube dual heated wire breathing system, 10 mm, paediatric	37704	Ila
8	4538850	Seturi de circuite respiratorii	Intersurgical	Flextube single heated wire breathing system, 15 mm , paediatric	37706	Ila
9	4504850	Seturi de circuite respiratorii	Intersurgical		37706	Ila
10	2811000	Accesorii pentru circuite respiratorii	Intersurgical	Reservoir bag, 1L with anti occlusion cage mount, 15F neck	34877	Ila

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

Page 1 of 3



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



[Handwritten signature]

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



0005

Authorised by

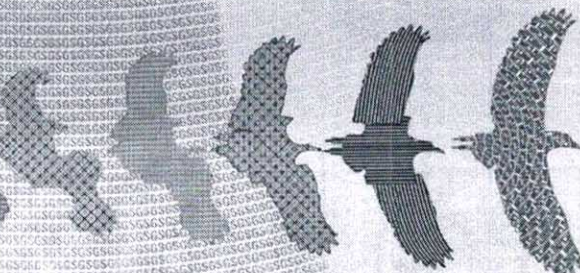
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 9001:2015 0421

Page 1 of 1



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Certificate GB06/70658

SGS

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

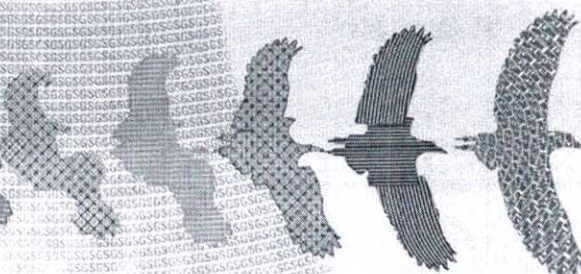
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 14001:2015_0421

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



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)

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 11
Valid from 1 January 2021
DCIGEL.DOC

Appendix for EU Declaration of Conformity Group: DCIGEL.DOC

Product Code	Product Description
8201000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1
8202000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.0, SMALL PAEDIATRIC, 10-25KG
8203000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 3, SMALL ADULT, 30-60KG
8204000	I-GEL, MEDIUM ADULT, SUPRAGLOTTIC AIRWAY, SIZE 4 (50-90KG)
8205000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 5
8215000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1.5, INFANT, 5-12KG
8225000	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.5,
8603000	I-GEL® PLUS, SUPRAGLOTTIC AIRWAY, SIZE 3, SMALL ADULT, 30-60KG
8604000	I-GEL® PLUS, SUPRAGLOTTIC AIRWAY, SIZE 4, MEDIUM ADULT, 50-90KG
8605000	I-GEL® PLUS, SUPRAGLOTTIC AIRWAY, SIZE 5, LARGE ADULT, 90+KG
8703000	I-GEL O2 RESUS PACK, SIZE 3
8703030	I-GEL O2 RESUS PACK - SIZE 3
8704000	I-GEL O2 RESUS PACK, SIZE 4
8704030	I-GEL O2 RESUS PACK - SIZE 4
8705000	I-GEL O2 RESUS PACK, SIZE 5
8705030	I-GEL O2 RESUS PACK - SIZE 5
8800000	AIRWAY SUPPORT STRAP

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

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)

Monitoring Tubes

These are class IIA medical devices, in accordance with rule 2 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 DCMONTUB.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 16
Valid from 1 January 2021
DCMONTUB.DOC

Appendix for Declaration of Conformity Group: DCMONTUB.DOC

Product Codes:

2720000	2720001	2720003	2720004	2720006
2721000	2721003	2722000	2723000	2723002
2723007	2723008	2725000	2725001	2725006
2725007	2725008	2725100	2730000	2731000
2731001	2731005	2732000	2732003	2732005
2732100	2733000	2734000	2734001	2734002
2734003	2734100	2734101	2735000	2735001
2737000	2737001	2737002	2738000	2740000
2740003	2740004	2740005	2740006	2741000
2741003	2741004	2741005	2741006	2742000
2743000	6216000	6216007	6216008	6216009
6216010	6216011	6216012	6216014	

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)

Anaesthetic Breathing 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 codes - 37704, 37021

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 DCABS.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.



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Duly authorised for and on behalf of Intersurgical Ltd
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Issue 23

Valid from 03 May 2021

DCABS.DOC

Appendix for Declaration of Conformity Group: DCABS.DOC

Product Codes:

1525800	1526000	1526003	1526004	2000160S
2000161S	2000218	2000258	2001009	2001010
2001012	2003005	2009202	2009209	2010000
2010000S	2010011	2010061	2010062	2010067
2010071	2010073	2010079	2010081	2010085
2010088	2010092	2010093	2010094	2010096
2010099	2010209	2010212	2010213	2010214
2010220	2010221	2010233	2010237	2010240
2010242	2010245	2010248	2010250	2010254
2010257	2010258	2010259	2010260	2010270
2010271	2010273	2011000	2011006	2011012
2011015	2011016	2011017	2011021	2011023
2011046	2011049	2011053	2011058	2013000
2013006	2013015	2013016	2013020	2013021
2013022	2015000	2016115	2016120	2016130
2102000	2102001	2105000	2105001	2106000
2106002	2108000	2108000S	2108002	2108005S
2108008	2108028	2108031	2108036	2108037
2108038S	2108039	2108042	2108043	2108044
2108045	2108046	2108048S	2108050	2108052S
2110000	2110003	2110004	2110005	2112000
2112011	2112012	2115000	2115009	2115011
2115013	2115015	2116000	2117000	2117004
2119001	2119002	2120000	2120019	2121000
2121000S	2121002	2121004	2121005	2121011
2121014	2121019	2121024	2121035	2121042
2121043	2121045	2121047	2121048	2121052

2121053	2122000	2122007	2122010	2122011
2122012	2122017	2122019	2123000	2123000S
2123005S	2123006S	2124000	2124000S	2124005S
2124006	2126000	2126001	2126004	2140000
2141000	2141001	2141004	2141009	2142000
2142002	2142003	2142005	2142007	2142010
2142014	2142015	2142016	2142017	2142024
2142026	2142027	2142028	2142029	2142030
2142034	2142035	2142040	2142044	2142045
2142048	2142049	2142050	2142051	2142052
2142053	2142058	2142062	2142082	2142083
2142085	2142086	2142091	2143000	2143001
2143002	2143017	2143036	2144000	2145000
2145001	2150000	2150001	2150160S	2151000
2151000S	2151001	2151003	2151008	2151020
2151161S	2151800	2152000	2152011	2153000
2153004	2153005	2154000	2154000S	2154002
2154006	2154014	2154017	2154023	2155000
2155001	2155003	2155006	2156000	2156003
2156004	2156005	2156006	2156007	2156008
2157000	2157001	2157004	2157007	2157008
2158000	2158007	2158008	2158160S	2161000
2162000	2163000	2164000	2164001	2164002
2165000	2165001	2165002	2165006	2600001
2611004	2611005	2611007	2612000	2612001
2612002	2612003	2612010	2612011	2612012
2612013	2620001	2620023	2630001	2820006s
2900000	2900000S	2900002	2900005	2900007
2900008	2900009	2900020	2900021	2900023

2900025	2900027	2900037	2900039	2900040
2900042	2900047	2900049	2900050	2900051
2900052	2900055	2900058	2900062	2900066
2900071	2900075	2900076	2900079	2900161S
2901000	2901000S	2901002	2901005	2901007
2901008	2901009	2901011	2901012	2901013
2901017	2901018	2901021	2902000	2902000S
2902001	2902002	2902005	2902012	2902014
2902015	2902016	2902017	2902018	2902019
2902021	2902022	2902026	2902028	2903000
2903001	2903003	2903004	2903005	2903005S
2903006	2903007	2903008	2903010	2903014
2903015	2903018	2903019	2903020	2903023
2903026	2903027	2910000	2911000	2920000
2920001	2920010	2920011	4000003	4050020
4500006	4500007	4500017	4500018	4500027
4500030	4500037	4500046	4512000	5000007
5000012	5000019	5000022	5000039	5000062
5000063	5000064	5003001S	5003002S	5007009
5007010	5007011	5007012	5008006	5008009
5008015	5008019	5008021	5009007	5009011
5009019S	5009022	5009025S	5009026S	5009039
5009041	5009044	5009058	5009068	5010003
5011000	5011001S	5011005	5011008S	5011009
5015004	5015005	5016001	5016005	5016007
5016011	5016012	5016013	5016017	5017002
5017005	5154000S	5202001	5209002	5209009
5500001	5500004S	5500005S	5500007S	5500008S
5500009S	5500012S	5503002	5512001	5512009

5512012	6089000	6202002	6202005	6202014
6203009	6203011	6203012	6203014	6203016
6203018	8746001	8746004	8746006	8746008
8746015	8790015	8790606	8790607	8790608
9317000	9318000	9319000	9320000	RM21323

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)

Heated Wire Breathing Systems, Heated Wires and Heated Wire Accessories

These are class IIa devices, in accordance with rule 9 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)

GMDN codes – 37706, 64392

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 DCHW.DOC.

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Issue 20
Valid from 09 December 2021
DCHW.DOC

Appendix for Declaration of Conformity Group: DCHW.DOC

Product Codes:

2025000	2025006	2025007	2025012	2025100
2025131	2025310	2025310S	2025312	2026000
2026053	2026100	2026131	2026310	2026310S
2026311	2026314	2026316	2027310	2031000
2031004	2031006	2032000	2036074	2038001
2050003	2050004	2050310	2051000	2060000
2060310	2066310	2083005	2083014	2231000
2231002	2231011	2234005	2235000	2237000
2240000	2331000	2332000	2332001	2334000
2334001	2335000	2431000	2432000	4061009
4071000	4072000	4113851	4504013	4504017
4504018	4504810	4504850	4506850	4507850
4508810	4508850	4508851	4509002	4509003
4509004	4509006	4509007	4509013	4509810
4509850	4515850	4516811	4516812	4516850
4519810	4523850	4525850	4526850	4527850
4538004	4538810	4538850	4539810	4539850
4539852	4540810	4554810	4554850	4555850
4558810	4560810	4609004	4609005	4609013
4609810	4609850	4639810	4639811	4639850
4709001	4709002	4709003	4709005	4709012
5015008	5025000	5025310	5025310S	5026000
5026310	5026310S	5068017	5068810	5068850
5068851	5069000	5071000	5072000	5191085
5191850	5191852	5194850	5504810	5504820
5504850	5505850	5506850	5507850	5508004
5508810	5508850	5509810	5509850	5510810

5510811	5510850	5515850	5518850	5519850
5520850	5568810	5568850	5600000	5601000
5603000	5604000	5609003	5609810	5609850
5619810	5619850	5804013	5808001	5808005
5809001	6003004	6068810	6090810	6091810
6091850	6122810	6122850	6222810	6358000
6390810	6392810	6392850	6393810	6431008
6431014	6457001	RM21335	RM21336	