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

Digitally signed by Iurchevici Valeriu
Date: 2022.07.01 15:40:56 EEST
Reason: MoldSign Signature
Location: Moldova

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 GB/PC 04303

Authorised by

Pieter Wetenings
Certification Manager

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 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 Flextube Flexible Tubing
• 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 CO2 Asorbents and Anaesthesia Systems containing Absorbents
• 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
• Sterile Guedel Airways

Additional facilities

UAB Intersurgical, Arnionių 60, LT-18170 Pabradė, Lithuania

Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

EC Certificate Full Quality Assurance System: GB95/7676

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 04 October 2018 until 26 November 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 October 2020
Issue 28. 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

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 28

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
• Non-sterile electrically powered moisture condenser for breathing systems

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

Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

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

ISO 9001: 2008 ISO 13485: 2003

UAB Intersurgical
Amonių g. 60, Pabrade, LT-18170, Lithuania
T: +370 387 66611 F: +370 387 66622
info@intersurgical.lt www.intersurgical.lt

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

LIETUVOS RESPUBLIKA * REPUBLIC OF LITHUANIA *
UAB
INTERSURGICAL
ŠVENČIONIŲ R. * PABRADĖ *

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ
«ECHIPAMED-PLUS»
IDNO 1003600077677

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

Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference
DW-legal / 119/13

Phone
+49 451 882-2471

E-mail
Erika.Wagner@draeger.com

Manufacturer's Authorization

09.02.2021

We, **Drägerwerk AG & Co. KGaA**, Moislinger Allee 53-55, 23558 Lübeck, Germany, who is an established and reputable manufacturer of medical equipment, having factories at Lübeck (Germany), Telford (United States), Andover (United States) and Shanghai (China), do hereby declare that

"Echipamed-Plus" SRL
Valea Trandafirilor 24 "B", of. 80
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights of Drägerwerk AG & Co. KGaA in the territory of the Republic of Moldova.

We declare that the above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their own name and on their own account.

This authorization letter will remain valid until 31.12.2021.

Duly authorized to sign this Authorization on behalf of

Drägerwerk AG & Co. KGaA

Drägerwerk AG & Co. KGaA Dräger Moislinger Allee 53-55 23558 Lübeck, Germany

Claus Martin Baumann
Authorized representative

Thomas Engler
Authorized representative

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

"ECHIPAMED-PLUS" SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA IDNO 1003600071677

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Dräger

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck
Germany

for the Scope of application

Design and development, production and distribution of diagnostic and therapeutic medical devices and installations as well as consulting and services in the field of medical technology

Revalstraße 1, 23560 Lübeck
Germany

for the Scope of application

Production and distribution of diagnostic and therapeutic medical devices and installations

has established and applies
a Quality Management System.

An audit was performed, Order No. **707037695**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-01-15** until **2024-01-14**.

Certificate Registration No.: **12 100 49423 TMS**.

Head of Certification Body
Munich, 2021-01-13

DAkkS Deutsche Akkreditierungsstelle D-ZM-16113-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010578 0031 Rev. 01

Holder of Certificate: **Drägerwerk AG & Co. KGaA**
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 010578 0031 Rev. 01

Report No.:	713193628
Valid from:	2021-01-18
Valid until:	2024-01-13

Date, 2021-01-18

Christoph Dicks
Head of Certification/Notified Body

«ECHIPAMED-PLUS» IDNO 1003600077677

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010578 0031 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010578 0037 Rev. 01

Manufacturer:

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Facility(ies):

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Product Category(ies):

**Anaesthetic equipment with standard accessories,
Infusion equipment with standard accessories,
Pediatric equipment with standard accessories,
Lung ventilator equipment with standard accessories,
Monitoring equipment with standard accessories,
Equipment for suction, breathing-, inhalation-, oxygen- and aerosol-therapy with standard accessories,
Medical supply units and terminal units for pressurized medical gases and vacuum,
Pipelines for compressed medical gases and vacuum,
Anaesthetic gas scaving systems, Components for medical gas management systems, Software for diagnosis based on clinical data incl. patient data, monitoring and device parameter, Visualization, diagnostic and therapeutic software for anesthesia and respiratory devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713162398

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17