

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.

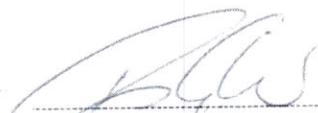
We declare that the above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their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


Claus Martin Baumann
Authorized representative


Thomas Engler
Authorized representative

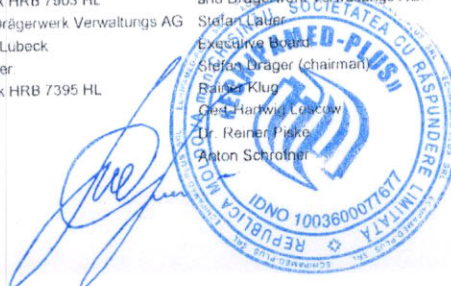


Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE 33 030
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lohr
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gerd Harwig, Lothar
Dr. Reiner Piske
Anton Schröder



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



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





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:



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

C. Dicks

Christoph Dicks

Head of Certification/Notified Body



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
Mölsinger 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

./.





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 scavenging 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

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

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



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

Page 2 of 3



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

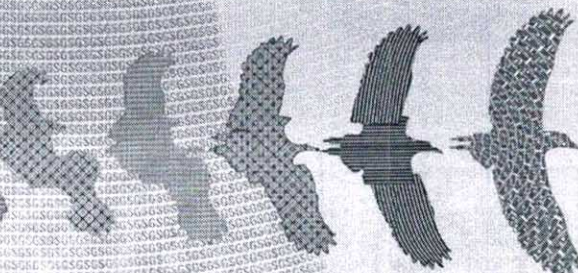
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 9001:2015 0421

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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

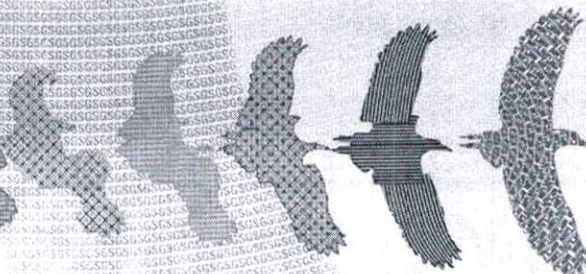
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 14001:2015_0421

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SGS



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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





EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Manufacturer: FIAB SpA

Registered address: Via Costoli 4, 50039 Vicchio (FI), Italia

Single Registration Number: IT-MF-000005988

Basic UDI-DI: 803300326208000001PF

Product name/ Intended Purpose: Fully gelled electrodes for neurostimulation

Models: See list in Attachment

Technical Documentation File: TDF 208

Risk Class (MDR Annex VIII): I

Conformity assessment procedure performed: Annex IV (EU Declaration of Conformity)

Technical standards and/or
Common Specifications applied:

EN 1041 [2008/A1:2013] - EN ISO 10993-1 [2018] - EN
ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO
15223-1 [2016]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives, and are latex free

Signature:

Vicchio, 01/07/2021

Alberto Calabrò
Managing Director

Declaration Code EU-00000049-208

First issued: 09/06/2021

Cod 99500038MD4B

Last revised: 30/06/2021

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EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Attachment of EU Declaration of Conformity – List of models

PG100 - PG200 - PG200W - PG200WN - PG470 - PG470/MIC - PG470L - PG470LN - PG470N - PG470N/500 - PG470W - PG470WN - PG471 - PG471/40 - PG471/40N - PG471/40W - PG471/40WN - PG471/50 - PG471/50W - PG471/50W-16 - PG471/50WN - PG471/63W - PG471/63WN - PG471L - PG471N - PG471W - PG471WN - PG472 - PG472/2C - PG472/90 - PG472/90W - PG472N - PG472W - PG472W2 - PG472WN - PG473 - PG473/2 - PG473/2N - PG473L - PG473LN - PG473N - PG473W - PG473W2 - PG473W2N - PG473W2N/DUE - PG473WN - PG474 - PG474L - PG474N - PG474W - PG474WN - PG475 - PG475L - PG475LN - PG475W - PG476 - PG476L - PG476N - PG476W - PG477 - PG477N - PG477W - PG479/32 - PG479/32N - PG479/32W - PG479/32WN - PG479/50 - PG479/50N - PG479/50W - PG479/50WN - PG479/75 - PG479/75W - PG479/75WN - PG479OVW - PG480/95W2 - PG490 - PG490N - PG500 - PG691WN - PG771/50 - PG771/50W - PG772/902 - PG772/90W - PG774W - PG871/40W - PG871/50 - PG871/50W - PG873 - PG873N - PG873W - PG873W2 - PG874W - PG879/32N - PG879/32W - PG879/50W - PG879/75 - PG880/95W2 - PG880/95W2N - PG890W

Declaration Code EU-00000049-208

First issued: 09/06/2021

Cod 99500038MD4B

Last revised: 30/06/2021

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