Corrigendum to Certificate Certificate GB19/964232

Intersurgical Ltd.

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

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)

Authorised by

Global Medical Devices 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

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Date: 2024.09.20 13:27:08 EEST
Reason: MoldSign Signature
Location: Moldova
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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

This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 8

Correction Date	Correction
Change approved by SGS on 11 January 2022	The client is removing one of their additional sites Unit 3 Mollay Millars Bridge, RG41 2WY
Change approved by SGS on 08 November 2022	This client is removing one of their additional facilities: Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

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.

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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:
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Nebulising System Delivery Sets
Suction and Irrigation Oral Care Toothbrush
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Breathing Systems Reservoir Bags
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Carbon Dioxide Absorbents
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Sterile Endotracheal Tubes
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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

Intersurgical Ltd
Crane House, Molly Millars Lane
Wokingham, Berkshire
RG41 2RZ
UK

04/09/2023

Confirmation Letter Reference: CLNB1639 GBPC04303

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Intersurgical Ltd
Crane House, Molly Millars Lane
Wokingham, Berkshire
RG41 2RZ
UK
SRN number: GB-MF-000004798

Authorised Representative
UAB Intersurgical
Arnionių g. 60
LT-18170 Pabradė,
Lithuania
SRN number: LT-AR-000003907

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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	IIa	N/A	GB19/964232; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05030267ABSL6 -Aerosol and Oxygen Face Masks 05030267AEROXY65 Anaesthetic Face Masks 05030267AMSKBX Sterile Endotracheal Tube Introducer and Sterile Airway Stylets 05030267BOUGCE Sterile and Non-Sterile Breathing Systems 05030267BS2M Non-Heated Respiratory Bubble Humidifier 05030267BUBHUM6E Sterile and Non-Sterile Catheter Mounts 05030267CATHMT3K Sterile and Non-Sterile Breathing System Connectors 05030267CONNR8V Sterile and Non-Sterile Respiratory Filters 05030267FILTER6S Breathing System Flexible Tubing 05030267FLEXTU8H High Concentration Oxygen Face Masks			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05030267HICON7E Sterile and Non-Sterile Heat and Moisture Exchangers 05030267HMEME Sterile and Non-Sterile HME Filters 05030267HMEFBU Sterile and Non-Sterile Inspiratory Line Humidification Chambers 05030267HUMCHA4 Sterile I-gel Supraglottic Airways 05030267IGELBH Sterile Laryngeal Airways 05030267LMAMS Gas Sampling / Monitoring Respiratory Tubing 05030267MONTUBCM Sterile and Non-Sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads) 05030267HW3F Electrically Powered Moisture Condenser, 05030267INTCOOLDZ Nasal Cannulae 05030267NACAN6E			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Nebulising System Delivery Sets 05030267NEBME Suction and Irrigation Oral Care Toothbrush 05030267ORANGE9K Oxygen Administration Tubing 05030267OXYTUBJX Repeated Use Breathing Systems 05030267REPSYSCX Breathing Systems Reservoir Bags 05030267RESBAG7X Manual Pulmonary Resuscitation Systems 05030267RESUSDC Carbon Dioxide Absorbents 05030267SODAE6 Sterile and Non-Sterile Tracheal Suction Systems 05030267SUCSYSFZ Sterile Endotracheal Tubes 05030267TRACTUBFN Venturi Valves and Venturi Valve Face Mask Kits 05030267VNTURIHK Wall Humidifier Nebuliser 05030267WALNEB8Z			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Breathing System Water Traps 05030267WT4N CPAP Bi-level Nasal Masks and NIV Face Masks 05030267CPNVMASKN6 Pressure Limiting Valves 05030267PLVALVEGW Peep Valves 05030267PVALVECF One Way Directional Valves 05030267OWVALVELU Infant Nasal CPAP Breathing System 05030267NFLOWAS Oxygen Recovery Kits 05030267OXYRECH7 Endoscopy Molar Bite Block 05030267BITEBLOCKR9 Carbon Dioxide Cuvette 05030267STREAMMONBW			
Sterile Guedel Airways 05030267GUEDEL6W	Is	N/A	GB19/964232; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/04	Version 1	Initial issue

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