INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

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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)
GMDN code: 45036
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 15
Valid from 17 September 2024
DCIGEL.DOC

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Appendix for Declaration of Conformity Group: DCIGEL.DOC

Product Codes:

8201000	8202000	8203000	8204000	8205000
8215000	8225000	8603000	8604000	8605000
8703000	8703030	8704000	8704030	8705000
8705030	8800000	8803000	8803030	8804000
8804030	8805000	8805030	8903000	8904000
8905000				

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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Intersurgical Ltd
Manufacturer address and contact details	Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ United Kingdom Tel: +44 (0) 118 9656 300 Fax: +44 (0) 118 9656 356
Single Registration Number (SRN) (if available)	GB-MF-000004798

Authorised Representative name (if applicable)	UAB Intersurgical
Authorised Representative address and contact details	Arnionių 60, Pabradė, LT-18170, Lithuania Tel: +370 387 66611 Fax: +370 387 66622
Single Registration Number (SRN) (if available)	LT-AR-000003907

Notified body name (if applicable)	SGS Belgium NV □ See attached schedule
Notified body number (if applicable)	1639 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	GB19/964232 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 November 2023 □ See attached schedule
End date of extended validity/transition period	31 December 2028 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☑ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.

The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	Intersurgical Ltd.
Location & Date:	Wokingham, 5 October 2023
Signature, Print Name, Title:	 Ivan Seniut Group Quality and Regulatory Affairs Director Duly authorised for and on behalf of Intersurgical Ltd
Contact Details (at least email):	00 370 38766 609 is@intersurgical.co.uk

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile and Non-Sterile Anaesthetic Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Aerosol and Oxygen Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Anaesthetic Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Endotracheal Tube Introducer and Sterile Airway Stylets	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Non-Heated Respiratory Bubble Humidifier	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile	GB19/964232	26 November 2023	SGS Belgium	SGS Belgium NV,	31 December	Not applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Catheter Mounts			NV, Notified Body 1639	Notified Body 1639	2028	
Sterile and Non-Sterile Breathing System Connectors	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Respiratory Filters	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing System Flexible Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
High Concentration Oxygen Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Heat and Moisture Exchangers	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile HME Filters	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Inspiratory Line Humidification Chambers	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile I-gel Supraglottic Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Laryngeal Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Gas Sampling/Monitoring Respiratory Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Sterile and Non-Sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads)	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Electrically Powered Moisture Condenser	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Nasal Cannulae	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Nebulising System Delivery Sets	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Suctions and Irrigation Oral Care Toothbrush	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Oxygen Administration Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Repeated Use Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing Systems Reservoir Bags	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Manual Pulmonary Resuscitation Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Carbon Dioxide Absorbents	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Sterile and Non-Sterile Trachseal Suction Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Endotracheal Tubes	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Venturi Valves and Venturi Valve Face Mask Kits	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Wall Humidifier Nebuliser	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing System Water Traps	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
CPAP Bi-level Nasal Masks and NIV Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Pressure Limiting Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Peep Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
One Way Directional Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Infant Nasal CPAP Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Oxygen Recovery Kits	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Endoscopy Molar Bite Block	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Carbon Dioxide Cuvette	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Guedel Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable