

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

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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)
<u>Sterile and Non-Sterile Anaesthetic Breathing Systems</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Aerosol and Oxygen Face Masks</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Anaesthetic Face Masks</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Sterile Endotracheal Tube Introducer and Sterile Airway Stylets</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Sterile and Non-Sterile Breathing Systems</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Non-Heated Respiratory Bubble Humidifier</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium NV, Notified Body 1639</u>	<u>SGS Belgium NV, Notified Body 1639</u>	31 December 2028	<u>Not applicable</u>
<u>Sterile and Non-Sterile</u>	<u>GB19/964232</u>	<u>26 November 2023</u>	<u>SGS Belgium</u>	<u>SGS Belgium NV,</u>	31 December	<u>Not applicable</u>

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)

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

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

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

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