EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Blvd Morrisville NC, 27560 USA
Authorized Representative Name and Address:	TFX Medical Ltd. IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath, Ireland
Notified Body Name and Address:	☐ *Class I: Not Applicable* ☒ *Class Is, Im, IIa, IIb, III* SGS Belgium NV, SGS House, Noorderlaan 87 2030 Antwerp, Belgium CE 1639

☐ **Class I**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex Annex I and Annex II (excluding Section 4) ISO 13485:*2016*, as implemented by the European Union's Medical Devices Regulations.

☒ **Class Is, Im, IIa, IIb, III**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex I and Annex II (excluding Section 4) and ISO 13485:*2016*, as implemented by the European Union's Medical Devices Regulations as verified by the Notified Body listed above:

Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.

Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Teleflex Medical agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

Product Name:	Anaesthesia and Respiratory Circuits Including Breathing Bags
Classification:	Class IIa Rule 2 (conventional circuits and accessories) Class IIb Rule 11 (Heated wire breathing circuits)
EC Certificates No.:	Canadian – 13485: 2016 – US18/81827522 Europe – 13485: 2016 – US97/10878.00 Europe – 93/42/EEC Certificate – US19/819943647.00 (CE 1639)

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Conformity Assessment Routes:	Annex II (excluding Section 4) of the MDD (93/42/EEC), Full Quality Assurance System

Product Code	Product Description	CE Distribution Date	GMDN Code
1607	Ventilator Circuit, 180cm w/Straight Tubing Connector	September 6, 2005	37706
1608	Ventilator Circuit, 180cm w/Elbow Tubing Connector	September 6, 2005	37706
1609	Ventilator Circuit, 180cm w/Dual Water Traps	September 6, 2005	37706
780-12	Universal Neonatal Breathing Circuit, 120cm w/Dual Water Traps	September 6, 2005	37706
780-07*	Breathing Circuit, Neonatal, 120cm w/Dual heated Limbs	September 6, 2005	37706
41650	Water Trap, Adult	September 6, 2005	41679
1680	100 in. length with cuttable cuffs	September 6, 2005	37706
41518	72 in. length with cuttable cuffs (CE-marked)	September 6, 2005	37706
780-19*	Inspiratory Limb Heated Wire Accessory	September 6, 2005	37706
780-33*	Breathing Circuit, 180cm, Inspiratory Heated Wire, Expiratory Water Trap	September 6, 2005	37706
780-34*	Breathing Circuit, 180cm, Inspiratory Heated Wire, Inspiratory & Expiratory Water Trap	September 6, 2005	37706
780-35*	Breathing Circuit, 180cm, Dual Limb Heated Wire	September 6, 2005	37706
780-36*	Breathing Circuit, 180cm, Dual Heated Wire, Inspiratory Expiratory Water Traps	September 6, 2005	37706
780-13*	Breathing Circuit, Neonatal, 120cm w/Inspiratory Heated Wire & Expiratory Limb Water Tap	September 6, 2005	37706
780-14*	Breathing Circuit, Neonatal, 120cm w/Inspiratory Heated Wire, Inspiratory & Expiratory Limb Water Tap	September 6, 2005	37706
780-15*	Breathing Circuit, Neonatal, 120cm w/Dual Heated Wire, Inspiratory & Expiratory Limb Water Tap	September 6, 2005	37706

**** Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment***

Name and Title of Approver:	*Nicole Schaffer* *Manager, Regulatory Affairs, Respiratory*
Signature of Approver:	
Date Approved:	16-Mar-2021
Site Where Approved:	Teleflex Medical 3015 Carrington Mill Blvd Morrisville NC, 27560 USA

European Classification Rationale

Conventional circuits and accessories are Class IIa devices per Rule 2: **Channelling or storing for eventual administration.**

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