EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	*Teleflex Medical* *3015 Carrington Mill Blvd* *Morrisville, NC 27560*
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 United Kingdom, Ltd. Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 0WA, U.K. CE 0120 ***Note: The SGS UK address is kept as a reference until NB number on labels is updated.*** *SGS Belgium NV* *SGS House Noorderlaan 87 2030* *Antwerp Belgium CE1639*

☐ **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 II (excluding Section 4) and *EN 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 and is in accordance with Annex II (excluding Section 4) and EN ISO 13485:2016, as implemented by the European Union's Medical Devices Regulations 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.

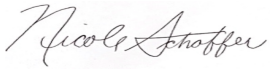
Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

For Use by Affiliates of Teleflex
This document contains proprietary information. It may not be reproduced without prior written approval.
>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Product Name:	Respiratory Therapy Adaptors and Connectors
Classification:	EU Classification: Class IIa, Rule 2 Canadian Class: Class 2
EC Certificates No.:	Canadian – ISO 13485:2016-US18/81827522 European – ISO 13485:2016, EN ISO 13485:2016 – US97/10878.00, Directive 93/42/EEC – US97/10879.00, US19/819943647.00
Conformity Assessment Routes:	Annex II (excluding Section 4) of the MDD (93/42/EEC), Full Quality Assurance System

Product Codes:	Product Description	CE distribution date:	GMDN Code
1674	Wye, Adult, W/O Port	6 September 2005	43435
1675	Wye, Adult, W/Temp Port	6 September 2005	43435
41660	Universal Wye Connector	6 September 2005	43435
41077	Aerosol Tee Adaptor	6 September 2005	61346
41639	Nebulizer Tee Connector	6 September 2005	61346
41648	Aerosol Tee Connector	6 September 2005	61346
41651	ISO Tee w/Anti-Spill	6 September 2005	61346
41666	Tee, Valved, Unidirectional	6 September 2005	35425
41668	Tracheostomy Tee Oxygenator	6 September 2005	61346
41664	One Way Valve, M/F	6 September 2005	35425
41665	One Way Valve, F/M	6 September 2005	35425
1423	Tubing Adaptor	6 September 2005	61346
1663	Adaptor, Soft cuff	6 September 2005	61346
1678	ISO Cuff Adaptor 22mm	6 September 2005	61346
41409	Large Tubing Connector	6 September 2005	61346
41420	Oxygen Supply Tubing Connector	6 September 2005	61346
41421	Universal Cuff Connector	6 September 2005	61346
41422	Multi-Adaptor, 22F/22M	6 September 2005	61346
41565	Mouthpiece	6 September 2005	44545
41640	Tubing Adaptor, 22F/22M	6 September 2005	61346
41642	Pressure Line Adaptor	6 September 2005	61346
41659	Adaptor, Metered Dose Inhaler	6 September 2005	61346
41669	Monitoring Adaptor	6 September 2005	61346
1623	Connector, Elbow	6 September 2005	61346
1624	Elbow, Gas Sampling	6 September 2005	61346
1632	Elbow, Norman Mask	6 September 2005	61346
1751	Metered Dose Inhaler Adptr.	6 September 2005	61346
1846	Anesthesia Circuit Oxygen Adapter	23 May 2018	61346
42555	Plastic Nipple and Nut (Green)	6 September 2005	61346
2557	Plastic Nipple and Nut (Clear)	27 November 2012	61346

**** 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, Regulatory Affairs Manager, Respiratory
Signature of Approver:	
Date Approved:	10 May 2021
Site Where Approved:	*Teleflex Medical* *3015 Carrington Mill Boulevard* *Morrisville, NC 27560*

For Use by Affiliates of Teleflex
This document contains proprietary information. It may not be reproduced without prior written approval.
>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Canadian Classification

The following devices meet Canadian requirements as listed:

Device	Canadian License #	Issue Date	Class of Product
42555	6321	1/28/2013	2
1674	6321	1/7/2003	2
1423	6321	1/7/2003	2
1663	6321	1/7/2003	2
1678	6321	11/8/2007	2
1623	6321	1/7/2003	2
1624	6321	1/7/2003	2
1632	6321	6/30/2004	2
1751	6321	1/28/2011	2

Product Description

Adaptors and Elbows
Tubular adaptors, straight or right-angled, possessing standard 15mm, 22mm, and/or non-standard conical connections. Select adaptors posses an additional port for environmental monitoring purposes.

Trache Tee Oxygenator
Configuration of an oxygen nipple adaptor, aerosol tee, and 6 inch CORR-A-FLEX tube.

MDI Adaptors
Tubular adaptor possessing standard 15mm or 22mm conical connections and a Metered Dose Inhaler (MDI) adaptor port.

Tees
T-shaped tubular adaptor possessing standard 15mm, 22mm, and/or non-standard conical connections. Select tees possess an anti-spill feature designed to minimize aspiration of liquids.

Valved Adaptors
Tubular adaptor possessing standard 15mm and/or 22mm conical connections and a uni-directional diaphragm flutter valve. Flow direction marked on outside of adaptor. Select valve possesses an additional port for environmental monitoring purposes.

Wyes
Y-shaped tubular adaptors possessing standard 15mm and 22mm conical connections. Two adjacent standard 22mm O.D. tubing connections comprise proximal end while distal end incorporates a standard 15mm I.D./22mm O.D. patient connection. Select wyes possess additional port(s) for environmental monitoring purposes.

Mouthpiece
Mouthpiece adaptor possessing standard 15mm to 22mm conical connection.

For Use by Affiliates of Teleflex
This document contains proprietary information. It may not be reproduced without prior written approval.
>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

	Composition Adaptors & Connectors: ABS, polycarbonate, acrylic, polystyrene, polyester, K-Resin, methyl styrene, styrene-butadiene copolymer, styrene-ethylene/butylene-styrene polymer, polypropylene, white dye, green dye, blue dye, ho stamp tape, and foil
Indications for Use	**Adaptors, Elbows, and Wyes** These devices are used to connect two components of a breathing system. If they are ported, they also monitor environmental conditions of a breathing system. **Trache Tee Oxygenator** The trache tee oxygenator allows administration of oxygen to an endotracheal or tracheotomy tube. **MDI Adaptors** MDI adaptors connect two components of a breathing system. They deliver aerosolized medication towards or away from patient for a reservoir effect. **Tees** These devices connect three components of a small volume nebulizer (SVN) system. **Valved Adaptors** The valved adaptors connect two components of a breathing system and allow for uni-directional gas flow within the breathing system. **Mouthpiece** The mouthpiece is used to provide a breathing passage between a breathing system and the patient.
Intended Use	**Adaptors, Elbows, and Wyes** Non-ported and ported: To connect two components of a breathing system Ported: To monitor environmental conditions of a breathing system **Trache Tee Oxygenator** Allows administration of oxygen to an end tracheal or tracheotomy tubes **MDI Adaptors** To connect two components of a breathing system and deliver aerosolized medication towards or away from patient for a reservoir effect **Tees** To connect three components of a small volume nebulizer (SVN) system. **Valved Adaptors** To connect two components of a breathing system and allow for uni-directional gas flow within a breathing system **Mouthpiece** To provide a breathing passage between a breathing system and patient
Contraindications	These products do not list contraindications on the labeling.
Manufacturing Site(s)	Manufacturing Site Name | Manufacturing Site Address

This document contains proprietary information. It may not be reproduced without prior written approval.
>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

	Teleflex Medical	Teleflex Medical Ave. Industrias No 5954 Parque Industrial Finsa Nuevo Laredo Tamaulipas, 88275 Mexico

Sterilizer

☒ N/A: The product is sold non-sterile.
☐ The product is sold sterile.

Sterilization Site Name	Sterilization Site Address
N/A	N/A

Standards

The Legal Manufacturer claims compliance with the following standards:

Number	Title	Revision/Year
93/42/EEC MDD	Medical Device Directive as amended by 2007/47/EC	2007
ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2016
EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2016
21CFR Part 820	Quality System Regulation	2011
BS EN ISO 14971	Medical devices – Application of risk management to medical devices	2012
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2010
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009
BS EN ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2013
ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements	2012
EN 980	Symbols for use in the labeling of medical devices	2008
EN 1041+A1:2013	Information supplied by the manufacturer of medical devices	2013
21 CFR Part 801	Labeling	2011
CMDR	Canada Medical Device Regulations	
ISO 5356-1	Anesthetic and Respiratory Equipment - Conical Connectors – Part 1: Cones and Sockets	2004
EU MEDDEV 2.7.1	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies	2016

For Use by Affiliates of Teleflex
This document contains proprietary information. It may not be reproduced without prior written approval.
>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<