EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Boulevard 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 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 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 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:	Non-Sterile Cannula and Supply Tubing
Classification:	Class IIa Rule 5 (Nasal Cannula) Class IIa Rule 2 (Oxygen Supply Tubing)
EC Certificates No.:	Canadian – ISO 13485:2016-US18/81827522 European – ISO 13485:2016, EN ISO 13485:2016 – US19/819943645.00, Directive 93/42/EEC –US19/819943647.00

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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
Nasal Cannulas			
1103	Cannula, Over-the-Ear, with Tubing	September 6, 2005	35201
1104	Cannula, Over-the-Ear, with Flared Prongs, Tubing	September 6, 2005	35201
41110	Cannula, Over-the-Ear, with STARLUMEN Tubing, Standard Connectors	September 6, 2005	35201
41820	Cannula, Softech, Adult with STARLUMEN Tubing, Standard Connectors	September 6, 2005	35201
41826	Cannula, Softech, Pediatric with STARLUMEN Tubing and Universal Connectors	September 6, 2005	35201
41828	Cannula, Softech, Infant with STARLUMEN Tubing	September 6, 2005	35201
1811	Cannula, 1103 w/25' Star-Lumen Tubing	October 22, 2014	35201
1813	Cannula, 1103 w/50' Star-Lumen Tubing	October 22, 2014	35201
1870	Softech Plus Adult Cannula,7' Green Star-Lumen Tubing	January 24, 2013	35201
1871	Softech Plus Pediatric Cannula,7' Green Star-Lumen Tubing	January 24, 2013	35201
1872	Softech Plus Infant Cannula,7' Green Star-Lumen Tubing	January 24, 2013	35201
1873	Softech Plus Neonatal Cannula,7' Green Star-Lumen Tubing	January 24, 2013	35201
1874	Softech Plus Adult, Cannula,7' Green Star-Lumen Tubing w/ Universal Connector	January 24, 2013	35201
1876	Softech Plus Pediatric, Cannula,7' Green Star-Lumen Tubing w/ Universal Connector	January 24, 2013	35201
1852	Softech Plus Adult Cannula,14' Green Star-Lumen Tubing w/ Universal Connector	January 24, 2013	35201
1853	Softech Plus Pediatric Cannula,14' Green Star-Lumen Tubing w/ Universal Connector	January 24, 2013	35201
1877	Softech Plus Adult Cannula,14' Green Star-Lumen Tubing	January 24, 2013	35201
1878	Softech Plus Pediatric Cannula, 14' Green Star-Lumen Tubing	January 24, 2013	35201
Oxygen Supply Tubing			
1115	Tubing, STARLUMEN, 2.1 m	September 6, 2005	12875
1900	Tubing, Oxygen Supply, 50'	October 22, 2014	12875
1986	Tubing, Tinted Star-Lumen, 30'	October 22, 2014	12875
1987	Tubing, Tinted Star-Lumen, 40'	October 22, 2014	12875
1988	Tubing, Tinted Star-Lumen, 50'	October 22, 2014	12875
1989	Tubing, Oxygen, 25'	October 22, 2014	12875
1991	Tubing, Oxygen Supply, 2.1 m	March 24, 2014	12875
41113	Tubing, STARLUMEN, 2.1 m	September 6, 2005	12875
41118	Tubing, STARLUMEN, 4.2 m	September 6, 2005	12875
41119	Tubing, STARLUMEN, 7.6 m	September 6, 2005	12875
41120	Tubing, STARLUMEN, 15.2 m	September 6, 2005	12875
41925	Oxygen Tubing w/ Universal Connector 2.1 m	September 6, 2005	12875
1679	Oxygen Tubing Water Trap	September 6, 2005	41679

**** 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***

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Name and Title of Approver:	Nicole Schaffer, Regulatory Affairs Manager, Respiratory
Signature of Approver:	
Date Approved:	07 June 2021
Site Where Approved:	*Teleflex Medical, Inc.* *3015 Carrington Mill Blvd.* *Morrisville, NC 27560* *USA*

Canadian Classification

The following devices meet Canadian requirements as listed:

Product Code	Product Description	Canadian License #	Issue Date	Class of Product
1103	Cannula, Over-the-Ear, with Tubing	7582	07/09/99	2
1104	Cannula, Over-the-Ear, with Flared Prongs, Tubing	7582	07/09/99	2
41110	Cannula, Over-the-Ear, with STARLUMEN Tubing, Standard Connectors	7582	10/15/12	2
1115	Tubing, STARLUMEN, 2.1 m	7588	07/09/99	2
1991	Tubing, Oxygen Supply, 2.1 m	7588	3/21/2014	2
41113	Tubing, STARLUMEN, 2.1 m	7588	8/24/09	2
41118	Tubing, STARLUMEN, 4.2 m	7588	10/15/12	2
41119	Tubing, STARLUMEN, 7.6 m	7588	10/15/12	2
41120	Tubing, STARLUMEN, 15.2 m	7588	10/15/12	2
41925	Oxygen Tubing w/ Universal Connector 2.1 m	7588	10/15/12	2
1679	Oxygen Tubing Water Trap	6321	11/1/2002	2
1811	Cannula, 1103 w/25' Star-Lumen Tubing	7582	10/22/2014	2
1813	Cannula, 1103 w/50' Star-Lumen Tubing	7582	10/22/2014	2
1900	Tubing, Oxygen Supply, 50'	7588	10/22/2014	2
1985	Tubing, Tinted Star-Lumen, 25'	7588	10/22/2014	2
1986	Tubing, Tinted Star-Lumen, 30'	7588	10/22/2014	2
1987	Tubing, Tinted Star-Lumen, 40'	7588	10/22/2014	2
1988	Tubing, Tinted Star-Lumen, 50'	7588	10/22/2014	2
1989	Tubing, Oxygen, 25'	7588	10/22/2014	2
41820	Cannula, Softech, Adult with STARLUMEN Tubing, Standard Connectors	94237	8/12/2016	2
41826	Cannula, Softech, Pediatric with STARLUMEN Tubing and Universal Connectors	94237	8/12/2016	2
41828	Cannula, Softech, Infant with STARLUMEN Tubing	94237	8/12/2016	2

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Product Description	**Nasal Cannulas** Nasal cannulas are designed to administer low-flow oxygen to the patient while providing part of the patient's inspiratory gas flow needs. Supplemental oxygen is provided from a nearby source or regulator and the remaining air is inhaled from the room environment. **Oxygen Supply Tubing** Oxygen supply tubing is an accessory item that connects a pressurized oxygen supply and a device, such as a nebulizer, mask, or cannula, which requires an oxygen supply. This product is both sold in bulk packaging and as a component included with other products. Supply tubing is made from soft, flexible PVC in a clear or green tint color. It is sold with either standard end connectors or the slightly larger "universal" connectors, which can connect directly to a threaded flow meter without the need for an adaptor.
Indications for Use	**Nasal Cannulas** Nasal cannulas are used to deliver a low flow of oxygen to the patient through the nasal passage. **Oxygen Supply Tubing** Oxygen supply tubing is used to deliver oxygen (or other medical gases) from a gas source to a patient, typically in conjunction with a mask, nasal cannula, or nebulizer.
Intended Use	**Nasal Cannulas** Nasal cannulas are used to deliver a low flow of oxygen to the patient through the nasal passage. **Oxygen Supply Tubing** Oxygen supply tubing is used to deliver oxygen (or other medical gases) from a gas source to a patient, typically in conjunction with a mask, nasal cannula, or nebulizer.
Contraindications	These products do not list any contraindications on the labeling.
Manufacturing Site(s)	See table below
Sterilizer	☒ N/A: The product is sold non-sterile. ☐ The product is sold sterile.

Manufacturing Site Name	Manufacturing Site Address
Manufacturing Facility for _Cat.No. 1103, 1104, 1104L, 1115, 1811, 1813, 1900, 1985, 1986, 1987, 1988, 1989, 1991, 41110, 41113, 41118, 41119, 41120, 41925, 1679:	Teleflex Medical Ave. Industrias No 5954 Parque Industrial Finsa Nuevo Laredo, Tamaulipas, 88275 Mexico
Manufacturing Facility for _Cat.No. 1870, 1871, 1872, 1873, 1874, 1876, 1852, 1853, 1877, 1878 41820, 41826, 41828. These products are Purchased Finished Goods (PFG) from Soundway. The Soundway DoC, CE Certificate and contract may be found in Section 2.	Ningbo Shengyurui Medical Appliances Co., Ltd (aka Soundway) No. 138, Binhaisi Road, Hangzhou Bay New Zone, Cixi City, Zhejiang Province China

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Sterilization Site Name	Sterilization Site Address

Standards

The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Name	Issue Date
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
ISO 14971	Medical devices – Application of risk management to medical devices	2019
EN ISO 14971	Medical devices – Application of risk management to medical devices	2019
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2020
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009
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	2016
EN 1041+A1:2013	Information supplied by the manufacturer of medical devices	2013
21CFR Part 820	Quality System Regulation	2011
21 CFR Part 801	Labeling	2011
CMDR	Canada Medical Device Regulations	
EU MEDDEV 2.7.1/rev 4	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under directives 93/42/EEC and 90/385/EEC	2016

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