

Legal Manufacturer Name and Address:	Teleflex Medical 2917 Weck Dr. Research Triangle Park, NC 27709 USA
Authorized Representative Name and Address:	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath Ireland
Notified Body Name and Address:	SGS United Kingdom, Ltd. Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 0WA, U.K. CE 0120

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 13485:2012, as implemented by the European Union's Medical Devices Regulations as verified by SGS:

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 13485:2003-US03/2838.00 European – EN ISO 13485:2012-US97/10878.00, Directive 93/42/EEC-US97/10879.00
Conformity Assessment Routes:	Annex IIa (excluding Section 4) of the MDD (93/42/EEC), full Quality Assurance System.

Product Codes:	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
1104L	Cannula with Flared Nasal Tips	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

EC Declaration of Conformity



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
1123	Tubing, Star-Lumen with Universal Connector	October 22, 2014	12875
1125	Tubing, Oxygen, 50' with Universal Connector	October 22, 2014	12875
1900	Tubing, Oxygen Supply, 50'	October 22, 2014	12875
1985	Tubing, Tinted Star-Lumen, 25'	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

Amanda Webb, Regulatory Affairs Manager, Respiratory

Name and Title

Signature

02 Mar 2017

Date

Canadian Classification	<u>Canada</u>			
	The following devices meet Canadian requirements as listed:			
	Device	Canadian License #	Issue Date	Class of Product
	1103	7582	07/09/99	2
	1104	7582	07/09/99	2
	41110	7582	10/15/12	2
	1115	7588	07/09/99	2
	1991	7588	3/21/2014	2
	41113	7588	8/24/09	2
	41118	7588	10/15/12	2
	41119	7588	10/15/12	2
	41120	7588	10/15/12	2
	41925	7588	10/15/12	2
	1679	6321	11/1/2002	2
	1811	7582	10/22/2014	2
	1813	7582	10/22/2014	2
	1123	7588	10/22/2014	2
	1125	7588	10/22/2014	2
	1900	7588	10/22/2014	2
	1985	7588	10/22/2014	2
	1986	7588	10/22/2014	2
	1987	7588	10/22/2014	2
	1988	7588	10/22/2014	2
	1989	7588	10/22/2014	2
	41820	94237	8/12/216	2
	41826	94237	8/12/216	2
	14828	94237	8/12/216	2
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	This product does not list any contraindications on the labeling.
Manufacturer	<u>Legal Manufacturer</u> Teleflex Medical 2917 Weck Drive Research Triangle Park, NC 27709 USA <u>Manufacturing Facility</u> <u>Manufacturing facility for Cat.No. 1103, 1104, 1104L, 1115, 1123, 1125, 1811, 1813, 1900, 1985, 1986, 1987, 1988, 1989, 1991, 41110, 41113, 41118, 41119, 41120, 41925, 1679:</u> Teleflex Medical Ave. Industrias No 5954 Parque Industrial Finsa Nuevo Laredo Tamaulipas, 88275 Mexico <u>Manufacturing facility for Cat.No. 1870, 1871, 1872, 1873, 1874, 1876, 1852, 1853, 1877, 1878 41820, 41826, 41828.</u> 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
Sterilizer	N/A - The Cannula and Supply Tubing are provided non-sterile.

*** Form History on File at Teleflex Medical Document Control RTP ***