# EC Declaration of Conformity

Teleflex MEDICAL

| | |
|---|---|
| **Legal Manufacturer Name and Address:** | **Teleflex Medical**<br>**2917 Weck Dr.**<br>**Research Triangle Park, NC 27709**<br>**USA** |
| **Authorized Representative Name and Address:** | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road, Athlone, Co. Westmeath**<br>**Ireland** |
| **Notified Body Name and Address:** | **SGS United Kingdom, Ltd.**<br>**Unit 202B, Worle Parkway,**<br>**Weston-Super-Mare, North Somerset,**<br>**BS22 0WA, U.K.**<br>**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)**<br>**Class IIa Rule 2 (Oxygen Supply Tubing)** |
| **EC Certificates No.:** | **Canadian – ISO 13485:2003-US03/2838 .00**<br>**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 |

Teleflex MEDICAL

| | | | |
|---|---|---|---|
| 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**

Teleflex MEDICAL

| | |
|---|---|
| **Canadian Classification** | Canada<br>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**<br>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.<br><br>**Oxygen Supply Tubing**<br>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**<br>Nasal cannulas are used to deliver a low flow of oxygen to the patient through the nasal passage.<br><br>**Oxygen Supply Tubing**<br>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**<br>Nasal cannulas are used to deliver a low flow of oxygen to the patient through the nasal passage.<br><br>**Oxygen Supply Tubing**<br>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. |
| | |

Teleflex MEDICAL

| | |
|---|---|
| **Contraindications** | This product does not list any contraindications on the labeling. |
| | |
| **Manufacturer** | Legal Manufacturer<br>Teleflex Medical<br>2917 Weck Drive<br>Research Triangle Park, NC 27709<br>USA<br><br>Manufacturing Facility<br><br>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:<br>Teleflex Medical<br>Ave. Industrias No 5954<br>Parque Industrial Finsa<br>Nuevo Laredo Tamaulipas, 88275<br>Mexico<br><br>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.<br>Ningbo Shengyurui Medical Appliances Co., Ltd (aka Soundway)<br>No. 138, Binhaisi Road,<br>Hangzhou Bay New Zone,<br>Cixi City, Zhejiang Province<br>China |
| | |
| **Sterilizer** | N/A - The Cannula and Supply Tubing are provided non-sterile. |

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