EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA
Authorized Representative Name and Address:	Teleflex Medical 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 *Insert Annex Number* and *Insert Version (ISO, BSI BS EN ISO, etc.)* ISO 13485:*Insert Publication Date*, 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, Annex V, Annex VII 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.

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Product Name:	**Small Volume Nebulizers**
Classification:	**Class IIb, Rule 11 (EU)** **Class 2, Rule 5 (CA)**
EC Certificates No.:	**European –** EN ISO 13485:2016-US97/10878.00 **Directive** 93/42EEC-US97/10879.00 (CE 0120)/ US19/819943647(CE1639) **Canadian** – MDSAP (ISO 13485:2016) – US18/81827522
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
41712	UP-DRAFT Small Volume Nebulizer w/ Adult Aerosol Mask	September 6, 2005	35457
41720	UP-DRAFT Small Volume Nebulizer w/ Mouthpiece	September 6, 2005	35457
41705	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask	September 6, 2005	35457
41707	UP-DRAFT II Small Volume Nebulizer w/ Pediatric Aerosol Mask	September 6, 2005	35457
41710	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask	September 6, 2005	35457
41730	UP-DRAFT II Small Volume Nebulizer	September 6, 2005	35457
41732	“T” UP-DRAFT Small Volume Nebulizer w/ Mouthpiece	September 6, 2005	35457
41883	MICRO-MIST Nebulizer w/ Tee, Tubing, Mouthpiece and Reservoir	September 6, 2005	35457
41890	MICRO-MIST Nebulizer, 22mm	September 6, 2005	35457
41892	MICRO-MIST Nebulizer, 22mm 22M/15F-22M/22F Tee & Mouthpiece	September 6, 2005	35457
41893	MICRO-MIST Nebulizer, 22mm w/ Adult Aerosol Mask	September 6, 2005	35457
41894	MICRO-MIST Nebulizer, 22mm w/ Pediatric Aerosol Mask	September 6, 2005	35457
41895	MICRO-MIST Nebulizer w/ Tee	September 6, 2005	35457
41897	Neb-U- Mist Side Draft Nebulizer w/ Tee & Mouthpiece	September 6, 2005	35457
41755	ISO-NEB Filtered Nebulizer System	September 6, 2005	35457
41745	In-Line-Neb Tee Kit	September 6, 2005	35457
41880	Pot For In-Line Neb-Tee Kit	September 6, 2005	35457

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41891	MicroMist Medication Nebulizer	September 6, 2005	35457
41898	Micro Mist Small Volume Nebulizer	September 6, 2005	35457
41893L	MICRO-MIST Nebulizer, 22mm w/ Adult Aerosol Mask	September 6, 2005	35457
41894L	MICRO-MIST Nebulizer, 22mm w/ Pediatric Aerosol Mask	September 6, 2005	35457
1734	"T" UP-DRAFT Small Volume Nebulizer w/ Mouthpiece, Reservoir and Tubing	September 6, 2005	35457
1895	Adult Neb-U-Mask	September 6, 2005	35457
1896	Pediatric Neb-U-Mask	September 6, 2005	35457
41560	Universal IPPB Circuit	September 6, 2005	35457

**** 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:	06 May 2021
Site Where Approved:	Teleflex Medical 3015 Carrington Mill Blvd Morrisville, NC 27709 USA

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European Classification Rationale
The following table indicates the Classification Rule used to determine the classification of the listed product codes in the small volume nebulizer family. The rationale for classification is provided:

Class IIb Products:

Product Codes:	Product Description	Rule	Rationale
41712	UP-DRAFT Small Volume Nebulizer w/ Adult Aerosol Mask	Rule 11	**Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body** Small Volume Nebulizers are used for intermittent aerosol therapy to deliver hydrating agents or other prescribed solutions for inhalation (Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body) Rule 11.
41720	UP-DRAFT Small Volume Nebulizer w/ Mouthpiece		
41705	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask		
41707	UP-DRAFT II Small Volume Nebulizer w/ Pediatric Aerosol Mask		
41710	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask		
41730	UP-DRAFT II Small Volume Nebulizer		
41732	"T" UP-DRAFT Small Volume Nebulizer w/ Mouthpiece		
41883	MICRO-MIST Nebulizer w/ Tee, Tubing, Mouthpiece and Reservoir		
41890	MICRO-MIST Nebulizer, 22mm		
41892	MICRO-MIST Nebulizer, 22mm 22M/15F-22M/22F Tee & Mouthpiece		
41893	MICRO-MIST Nebulizer, 22mm w/ Adult Aerosol Mask		
41894	MICRO-MIST Nebulizer, 22mm w/ Pediatric Aerosol Mask		
41895	MICRO-MIST Nebulizer w/ Tee		
41755	ISO-NEB Filtered Nebulizer System		
41745	In-Line-Neb Tee Kit		
41880	Pot For In-Line Neb-Tee Kit		
41891	MicroMist Medication Nebulizer		
41898	Micro Mist Small Volume Nebulizer		
41893L	MICRO-MIST Nebulizer, 22mm w/ Adult Aerosol Mask		
41894L	MICRO-MIST Nebulizer, 22mm w/ Pediatric Aerosol Mask		
1734	"T" UP-DRAFT Small Volume Nebulizer w/ Mouthpiece, Reservoir and Tubing		
1895	Adult Neb-U-Mask		
1896	Pediatric Neb-U-Mask		
41560	Universal IPPB Circuit		

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Canadian Classification

The following devices meet Canadian requirements as listed:

Product Code	Product Description	Canadian License #	Issue Date	Class of Product
41712	UP-DRAFT Small Volume Nebulizer w/ Adult Aerosol Mask	7584	10-15-2012	2
41720	UP-DRAFT Small Volume Nebulizer w/ Mouthpiece	7584	10-15-2012	2
41705	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask	7584	10-15-2012	2
41707	UP-DRAFT II Small Volume Nebulizer w/ Pediatric Aerosol Mask	7584	10-15-2012	2
41710	UP-DRAFT II Small Volume Nebulizer w/ Adult Aerosol Mask	7584	10-15-2012	2
41730	UP-DRAFT II Small Volume Nebulizer	7584	10-15-2012	2
41732	"T" UP-DRAFT Small Volume Nebulizer w/ Mouthpiece	7584	10-15-2012	2
41883	MICRO-MIST Nebulizer w/ Tee, Tubing, Mouthpiece and Reservoir	7584	8-24-2009	2
41890	MICRO-MIST Nebulizer, 22mm	7584	10-15-2012	2
41892	MICRO-MIST Nebulizer, 22mm 22M/15F-22M/22F Tee & Mouthpiece	7584	10-15-2012	2
41893	MICRO-MIST Nebulizer, 22mm w/ Adult Aerosol Mask	7584	10-15-2012	2
41894	MICRO-MIST Nebulizer, 22mm w/ Pediatric Aerosol Mask	7584	8-26-2004	2
41895	MICRO-MIST Nebulizer w/ Tee	7584	10-15-2012	2
41755	ISO-NEB Filtered Nebulizer System	7584	10-15-2012	2
41745	In-Line-Neb Tee Kit	7584	10-15-2012	2
41880	Pot For In-Line Neb-Tee Kit	7584	10-15-2012	2
41891	MicroMist Medication Nebulizer	7584	10-15-2012	2
41898	Micro Mist Small Volume Nebulizer	7584	10-15-2012	2
1734	"T" UP-DRAFT Small Volume Nebulizer w/ Mouthpiece, Reservoir and Tubing	7584	7-9-1999	2
1895	Adult Neb-U-Mask	79145	2-26-2009	2
1896	Pediatric Neb-U-Mask	79145	2-26-2009	2
41560	Universal IPPB Circuit	7574	10-15-2012	2

Product Description	**Small Volume Nebulizers** Small volume nebulizers (SVNs) are non-sterile, disposable devices used to aerosolize medication, for direct delivery to a patient's respiratory tract. These devices consist of a small jar to hold medicinal solutions, an internal jet orifice which produces the aerosol, an impingement dome that is often part of the cap and a spill-resistant cap with aerosol outlet port. Small volume nebulizers (SVN) are used in nebulization applications tested and calibrated to administer medicinal aerosols to the patient at a recommended flow rate which the patient inhales via mask or mouth piece attachment. When the patient inhales, the aerosol created from an internal jet inside the nebulizer jar, is intended to improve the patient's respiratory function. The nebulizer treatment can be administered to the patient at varying angles depending on patient's ability to lay, partially, or fully sit up for treatment.

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	Neb-U-Mask The Neb-U-Mask High Concentration system is a combination device that allows for the concurrent delivery of aerosolized medications and high concentrations of oxygen or heliox. The nebulizer connection features a valved port, which maintains a closed system when the nebulizer is not in use.
Indications for Use	Small volume nebulizers are intended to be used for intermittent aerosol therapy to deliver hydrating agents or other prescribed solutions for inhalation.
Intended Use	The Small Volume Nebulizers are used for intermittent aerosol therapy to deliver hydrating agents or other prescribed solutions for inhalation.
Contraindications	There are no contraindications for these devices.
Manufacturing Site(s)	Manufacturing Site Name: Teleflex Medical de Mexico, S. de R.L. de C.V. Manufacturing Site Address: 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:

Standards
The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Issue Date	Standard Name
ISO 13485	2016	Medical devices - quality management systems - requirements for regulatory purposes
EN ISO 13485	2016	Medical devices - quality management systems - requirements for regulatory purposes
ISO 14971	2007	Medical devices - application of risk management to medical devices
EN ISO 14971	2012	Medical devices - application of risk management to medical devices
ISO 10993-1	2009	Biological evaluation of medical devices part 1: evaluation and testing within a risk management process
ISO 10993-5	2009	Biological evaluation of medical devices part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-10	2014	Biological evaluation of medical devices part 10: Test for irritation and skin sensitization.
ISO 15223-1	2016	Medical devices - symbols to be used with medical device labels, labeling and information to be supplied - part 1: general requirements
93/42/EEC MDD	2007	Medical Device Directive as amended by 2007/47/EC
21CFR Part 820	2011	Quality System Regulation
CMDR		Canadian Medical Device Regulations
BS EN 1041 + A1	2013	Information Supplied by the Manufacturer of Medical Devices
ISO 5356-1	2015	Anesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets

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MEDDEV 2.7/1 Rev4	2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
ISTA 1 Series		Non-stimulation Intergrity Performance Tests – Procedure 1A: Packaged Product Weighing 150lbs. (68kg) or less.

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