EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015, Carrington Mill Blvd Morrisville, NC 27560
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.

Product Name:	**Disposable Humidifiers and Large Volume Nebulizers**
Classification:	**Class IIb Rule 11 for Large Volume Nebulizer** **Class IIa, Rule 2 for Disposable Humidifier** **Class IIa Rule 2 for Aerosol Drainage System with Tee**
EC Certificates No.:	**European –** EN ISO 13485:2016-US97/10878.00, Directive 93/42EEC- US19/819943647.00 (CE 1639) **Canadian** – MDSAP (ISO 13485:2016) – US18/81827522

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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
41770	Large Volume Nebulizer Variable Concentration	September 6, 2005	35457
3230	Disposable Humidifier, 500 mL, 4 psi	September 6, 2005	35113
41740	Aerosol Drainage System with Tee	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***

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

European Classification Rationale

The following table indicates the Classification Rule used to determine the classification of the listed product codes in the **Disposable Humidifiers and Large Volume Nebulizers** family. The rationale for classification is provided:

Class IIa Products:

Product Codes	Product Description	Rule	Rationale
Disposable Humidifier / Aerosol Drainage System with Tee			
3230	Disposable Humidifier, 500 mL, 4 psi	Rule 2	**Channelling or storing for eventual administration** Disposable Humidifier and Aerosol Drainage System with Tee are in the gas pathway and serve as a channel for the administration of humidification. The sterile water used for the generation of humidity is stored within the Disposable Humidifier.
41740	Aerosol Drainage System with Tee		
Class IIb Products:			
Large Volume Nebulizer			
41770	Large Volume Nebulizer Variable Concentration	Rule 11	**Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body** Nebulizer aerosolize sterile water stored within the nebulizer.

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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
3230	Disposable Humidifier, 500 mL, 4 psi	7372	7/7/1999	2
41770	Large Volume Nebulizer Variable Concentration	7569	10/15/2012	2
41740	Aerosol Drainage System with Tee	7404	10/15/2015	2

Product Description	**Large Volume Nebulizer** The **large volume nebulizers and disposable humidifiers** are durable plastic chambers that are filled with water and attached to an oxygen source to deliver humidified air to the patient. The air from an outside source travels through the water filled chamber creating turbulence, humidifying the air breathed in by the patient. The large volume nebulizer consists of a durable polypropylene jar with usable volume of 500mL, a lid with upper body assembly, which incorporates a standard wing nut for the oxygen flow meter connection, a room air entrainment collar for setting precise oxygen concentrations (from 28 percent to 98 percent), and an outlet port with aerosol tubing connection for output to the mask or patient delivery device. Each large volume nebulizer is individually wrapped and packaged 50 to a case. **Disposable Humidifier** The disposable humidifier consists of a transparent polypropylene jar to hold water, a green polystyrene lid, which incorporates a recessed outlet port, a silicone pressure relief valve, a polyethylene diffuser with flexible LDPE tubing, and a polypropylene flow meter nut. Each disposable humidifier is individually wrapped to protect product from dust and contamination and are packaged 50 per case. **Aerosol Drainage System** The aerosol drainage system consists of a tee fastened to a disposable drainage bag by means of vinyl tape and cable tie. Adaptors possess standard 22mm conical connections. Disposable bags have a 750cc capacity and a drainage port at the base. In addition, self-locking plastic chain attached to adaptor for securing system to stable object.
Indications for Use	The non-prefilled humidifiers and nebulizers are indicated when humidity needs to be added to the air flow going to a patient.
Intended Use	The **non-prefilled disposable humidifiers** add humidity in water vapor form to respiratory gases delivered to patients to make the gases more comfortable to breathe. The disposable humidifier (cat. no. 3230) incorporates a pressure relief valve with an audible alarm at 4 psi. The **non-prefilled disposable large volume nebulizers** add humidity in aerosol form to respiratory gases to make the gases more comfortable to breathe and assist in thinning and mobilizing secretions. The large volume nebulizer (cat. no. 41770) allows for the provision of humidified oxygen at selected oxygen concentrations from 28% and 98%. The **Aerosol Drainage System** is used to provide a means for collecting and draining condensate from open aerosolized oxygen administration circuits.

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Contraindications	These products do not list contraindications on the labeling.
Manufacturing Site(s)	Manufacturing Site Name: Teleflex Medical 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.

Standards
The Legal Manufacturer claims compliance with the following standards:

Number	Title	Revision/Year
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	2007
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	2009
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: Test for irritation and skin sensitization.	2014
ISO 8185	Respiratory Tract humidifiers for medical use – Particular requirements for respiratory humidification systems – Section 101: Humidification system output (applies only to REF 3230)	2007
ISO 15223-1	Medical devices - symbols to be used with medical device labels, labeling and information to be supplied - part 1: general requirements	2016
93/42/EEC MDD	Medical Device Directive as amended by 2007/47/EC	2007
21CFR Part 820	Quality System Regulation	
CMDR	Canadian Medical Device Regulations	
BS EN 1041+A1	Information Supplied by the Manufacturer of Medical Devices	2013
ISO 5356-1	Anesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets	2015
NB-MED/2.7/Rev4	Evaluation of Clinical Data. Chapter 2.7 Clinical Investigations, Clinical Evaluation	2016

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