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.

Product Name:	**AquaPak® Prefilled Humidifiers and Nebulizers**
Classification:	**Humidifier Adaptor:** Class IIa, Rule 2 **Humidifier Reservoirs:** Class IIa, Rule 5 **Humidifier Reservoir and Humidifier Adaptor Configurations:** Class IIa, Rule 2 **Nebulizer Adaptor:** Class IIb, Rule 11 **Nebulizer Reservoirs:** Class IIa, Rule 5

	Nebulizer Reservoir and Nebulizer Adaptor Configurations: Class IIb, Rule 11
EC Certificates No.:	**Canadian** – MDSAP (ISO 13485:2016) – US18/81827522 **European –** EN ISO 13485:2016-US97/10878.00, Directive 93/42EEC- US19/819943647.00
Conformity Assessment Routes:	Annex II (excluding Section 4) of the MDD (93/42/EEC), full Quality Assurance System.

Product Codes:	Product Description	CE Distribution Date:	GMDN Cod
Humidifier Adaptor			
400040	040 Humidifier Adaptor, Shelfpak	September 6, 2005	adpt: 61166
000-40F	Humidifier Adaptor, 040 Shelf Pak, French	September 6, 2005	adpt: 61166
Humidifier Reservoirs			
400301	Aquapak 301 Sterile Water, 340mL	September 6, 2005	water: 44706
400601	Aquapak 601 Sterile Water, 650mL	September 6, 2005	water: 44706
Humidifier Reservoir and Humidifier Adaptor Configurations			
400340	Aquapak 340 Sterile Water, 340mL w/040 Adaptor	September 6, 2005	water: 44706
400640	Aquapak 640 Sterile Water, 650mL w/040 Adaptor	September 6, 2005	water: 44706
003-40B	AquaPak 340 Sterile Water, 340 mL w/040 Adaptor, British Standard Thread	December 5, 2014	water: 44706
003-40F	Aquapak 340 Sterile Water, 340 ML w/040 Adaptor, French	September 6, 2005	water: 44706
006-40F	Aquapak 640 Sterile Water, 650 ML w/040 Adaptor, French	September 6, 2005	water: 44706
Nebulizer Adaptors			
403128	Nebulizer Adaptor 028	September 6, 2005	adpt: 61167
403133	Nebulizer Adaptor 033	September 6, 2005	adpt: 61167
031-28F	Nebulizer Adaptor 028, Sterile, Shelfpak	September 6, 2005	adpt: 61167
Nebulizer Reservoirs			
400400	Aquapak 400 Sterile Water, 440 mL	September 6, 2005	water: 44706
400405	Aquapak 405 Half Normal Saline, 440mL	September 6, 2005	saline: 44746
403700	Aquapak 700 Sterile Water, 760mL	September 6, 2005	water: 44706
403705	Aquapak 705 Half Normal Saline, 760mL	September 6, 2005	saline: 44746
403709	Aquapak 709 Full Normal Saline, 760mL	September 6, 2005	saline: 44746
404000	Aquapak 1000 Sterile Water, 1070mL	September 6, 2005	water: 44706
404045	Aquapak 1005 Half Normal Saline, 1070 mL	July 8, 2016	saline: 44746
Nebulizer Reservoir and Nebulizer Adaptor Configurations			
404428	Aquapak 428 Sterile Water, 440mL w/028 Adaptor	September 6, 2005	water: 44706
404433	Aquapak 433 Sterile Water, 440mL w/033 Adaptor	December 5, 2014	water: 44706
404435	Aquapak 435 Half Normal Saline, 440mL w/028 Adaptor	December 5, 2014	saline: 44746
403728	Aquapak 728 Sterile Water, 760mL w/028 Adaptor	September 6, 2005	water: 44706
403733	Aquapak 733 Sterile Water, 760mL w/033 Adaptor	December 5, 2014	water: 44706
403735	Aquapak 735 Half Normal Saline, 760mL w/028 Adaptor	December 5, 2014	saline: 44746
403770	Aquapak 770 Half Normal Saline, 760mL w/033 Adaptor	December 5, 2014	saline: 44746
404128	Aquapak 1028 Sterile Water, 1070mL w/028 Adaptor	September 6, 2005	water: 44706
404133	Aquapak 1033 Sterile Water, 1070mL w/033 Adaptor	December 5, 2014	water: 44706
404135	Aquapak 1035 Half Normal Saline, 1070mL w/028 Adaptor	December 5, 2014	saline: 44746
044-28F	Aquapak 428 Sterile Water, 440 ML w/028 Adaptor, French	September 6, 2005	water: 44706
037-28F	Aquapak 728 Sterile Water, 760 ML w/028 Adaptor, French	September 6, 2005	water: 44706

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

European Classification Rationale

The following table indicates the Classification Rule used to determine the classification of the listed product codes in the Pre-Filled Humidifier and Nebulizer Reservoirs (water and saline) with Adaptors family. The rationale for classification is provided:

Class IIa Products:

Product Codes:	Product Description	Rule	Rationale
Humidifier Adaptor & Humidifier Reservoir and Humidifier Adaptor Configurations			
400040	040 Humidifier Adaptor, Shelfpak	Rule 2	**Channelling or storing for eventual administration** Humidifier Adaptors are in the gas pathway and serve as a channel for administration of humidification. The sterile water used for the generation of humidity is stored within the Humidifier Reservoir.
000-40F	Humidifier Adaptor, 040 Shelf Pak, French		
400340	Aquapak 340 Sterile Water, 340mL w/040 Adaptor		
400640	Aquapak 640 Sterile Water, 650mL w/040 Adaptor		
003-40B	AquaPak 340 Sterile Water, 340 mL w/040 Adaptor, British Standard Thread		
003-40F	Aquapak 340 Sterile Water, 340 ML w/040 Adaptor, French		
006-40F	Aquapak 640 Sterile Water, 650 ML w/040 Adaptor, French		
Humidifier and Nebulizer Reservoirs			
400301	Aquapak 301 Sterile Water, 340mL	Rule 5	**Devices invasive with respect to body orifices** Humidifier and Nebulizer Reservoirs contain sterile water and saline to be delivered as humidification or aerosol for patient inhalation.
400601	Aquapak 601 Sterile Water, 650mL		
400400	Aquapak 400 Sterile Water, 440 mL		
400405	Aquapak 405 Half Normal Saline, 440mL		
403700	Aquapak 700 Sterile Water, 760mL		
403705	Aquapak 705 Half Normal Saline, 760mL		
403709	Aquapak 709 Full Normal Saline, 760mL		
404000	Aquapak 1000 Sterile Water, 1070mL		
404045	Aquapak 1005 Half Normal Saline, 1070 mL		

Class IIb Products:

Product Codes:	Product Description	Rule	Rationale
Nebulizer Adaptors & Nebulizer Reservoir and Nebulizer Adaptor Configurations			
403128	Nebulizer Adaptor 028	Rule 11	**Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body** Nebulizer Adaptors utilize compressed gas to aerosolize sterile water or saline stored within the Nebulizer Reservoirs.
403133	Nebulizer Adaptor 033		
031-28F	Nebulizer Adaptor 028, Sterile, Shelfpak		
404428	Aquapak 428 Sterile Water, 440mL w/028 Adaptor		
404433	Aquapak 433 Sterile Water, 440mL w/033 Adaptor		
404435	Aquapak 435 Half Normal Saline, 440mL w/028 Adaptor		
403728	Aquapak 728 Sterile Water, 760mL w/028 Adaptor		
403733	Aquapak 733 Sterile Water, 760mL w/033 Adaptor		
403735	Aquapak 735 Half Normal Saline, 760mL w/028 Adaptor		
403770	Aquapak 770 Half Normal Saline, 760mL w/033 Adaptor		

404128	Aquapak 1028 Sterile Water, 1070mL w/028 Adaptor		
404133	Aquapak 1033 Sterile Water, 1070mL w/033 Adaptor		
404135	Aquapak 1035 Half Normal Saline, 1070mL w/028 Adaptor		
044-28F	Aquapak 428 Sterile Water, 440 ML w/028 Adaptor, French		
037-28F	Aquapak 728 Sterile Water, 760 ML w/028 Adaptor, French		

Canadian Classification

The following devices meet Canadian requirements as listed:

Device	Canadian License #	Issue Date	Class of Product
003-40C	7571	1999-07-09	2
006-40C	7571	1999-07-09	2
037-28C	7571	2010-04-22	2
037-33C	7571	2010-04-22	2
037-39C	7571	2010-04-22	2
041-28C	7571	2010-04-22	2
044-28C	7571	2010-04-22	2
400040	7571	2012-10-15	2
403128	7571	2012-10-15	2
403133	7571	2015-02-13	2
000-40	7571	2003-01-02	2
031-28	7571	2009-01-22	2
031-33	7571	2009-01-22	2

Product Description	AQUAPAK® devices provide sterile water or sterile saline for inhalation therapy. Humidifiers add water vapor (molecular H2O) to a dry medical gas, whereas nebulizers generate aerosol, a fine mist of liquid water (or sodium chloride solution) that is suspended in the gas to be inhaled by the patient.
Indications for Use	AQUAPAK devices are intended to be used for respiratory therapy utilizing humidified gases or aerosolized water and saline solutions.
Intended Use	**<u>Humidifiers:</u>** Humidifiers are useful for increasing the water vapor content of dry, therapeutic gases to make them more comfortable to breathe. Humidity is commonly added to prevent drying and irritation of mucosal membranes along the patient's internal airway whenever inhalation therapy with a medical gas (such as oxygen) is indicated. **<u>Nebulizers:</u>** Nebulizers are used to produce aerosols, or gaseous suspensions of tiny liquid droplets. Like humidifiers, these devices are useful for hydrating the patient's respiratory tract. However, since nebulizers deliver the moisture in a mist of liquid particles rather than water vapor, the moisture can be delivered at a faster rate. Patients having especially thick or crusted secretions, artificial airways (including tubes which have recently been

	removed), inflammatory obstructions, or fiber optic bronchoscopy, may benefit from aerosol therapy. Nebulizer reservoirs may also be used in conjunction with a heater to raise the temperature of the inspired gas, which significantly increases its moisture-carrying capacity.
Contraindications	There are no contraindications for these devices.
Manufacturing Site(s)	

Manufacturing Site Name	Manufacturing Site Address
Teleflex Medical	900 W. University Drive **Arlington Heights**, IL 60004 USA
Teleflex Medical de Mexico, S. de R.L. de C.V.	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
Sterigenics	1003 Lakeside Drive Gurnee, IL 60031 USA *Gamma irradiation for individually sold nebulizer adaptors* 711 E. Cooper Court Schaumburg, IL 60173 USA *Gamma irradiation for humidifier adaptors (individually sold and kitted) and kitted nebulizer adaptors*
Teleflex Medical	900 W. University Drive **Arlington Heights**, IL 60004 USA *Aseptic Fill process for humidifier and nebulizer reservoirs*

Standards

The Legal Manufacturer claims compliance with the following standards:

Number	Title	Revision/Year
93/42/EEC MDD	Medical Device Directive as amended by 2007/47/EC	2007
MEDDEV 2.7/1 Rev4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	2016
ISO 13485 EN ISO 13485	Medical devices - quality management systems - requirements for regulatory purposes	2016 2016
EN ISO 14971	Medical devices - application of risk management to medical devices	2012

ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: requirements for materials, sterile barrier systems and packaging systems	2009
EN ISO 10993-1	Biological evaluation of medical devices part 1: evaluation and testing within a risk management process	2009
EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2013
EN ISO 11137-1	Sterilization of health care products - Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical device	2015
EN ISO 11137-2	Sterilization of health care products - Radiation-Part 2: Establishing the sterilization dose	2015
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Estimation of population of microorganisms on products	2006
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process	2009
BS EN 1041 + A1	Information supplied by the manufacturer of medical devices	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
CMDR	Canada Medical Device Regulations	
21 CFR Part 820	Quality System Regulation	
21 CFR Part 801	Labeling	
cUSP-NF	Current United States Pharmacopeia – National Formulary, Sterile Water for Inhalation and Sterile Sodium Chloride for Inhalation monograph.	
ISTA 1A	Non-Simulation Integrity Performance Tests**,** Packaged-Products weighing 150 lb (68 kg) or Less	
ISTA 2A	Partial Simulation Performance Tests**,** Packaged-Products weighing 150 lb (68 kg) or Less	

EC Certificate Full Quality Assurance System: Certificate US19/819943647.01

The management system of

Teleflex Medical

3015 Carrington Mill Blvd.
27560 Morrisville, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 October 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00.

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 06866

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Sterile Hem-o-lok and Vesolock Ligation Clips, Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesocclude Metal Ligation Clips Sterile Deknatel® PTFE pledgets. Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®). Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and polypropylene non-absorbable surgical sutures. Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures. Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures. Sterile Hem-o-lok Automatic Clip Appliers.nMetal Ligation System. Sterile and Non-sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, EFx endo fascial closure system (abdominal access), Sterile, EFx shield fascial closure system (abdominal access), Sterile, EFx classic fascial closure system (abdominal access) Sterile stainless steel surgical Sutures Sterile FORCE FIBER® surgical sutures. Sterile Chest drainage and autotransfusion systems, Sterile Thoracic Catheters, Sterile and Non-sterile Aortic Punch, Non-sterile Self Retaining Tissue retractor/blades Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.