## EC DECLARATION OF CONFORMITY

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|---|---|
| Legal Manufacturer Name and Address: | Teleflex Medical<br>3015 Carrington Mill Blvd.<br>Morrisville, NC 27560<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: | ☐ *Class I: Not Applicable*<br>☒ *Class Is, Im, IIa, IIb, III*<br><br>SGS Belgium NV,<br>SGS House, Noorderlaan 87<br>2030 Antwerp, Belgium<br>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<br>**Humidifier Reservoirs:** Class IIa, Rule 5<br>**Humidifier Reservoir and Humidifier Adaptor Configurations:** Class IIa, Rule 2<br>**Nebulizer Adaptor:** Class IIb, Rule 11<br>**Nebulizer Reservoirs:** Class IIa, Rule 5 |


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| | **Nebulizer Reservoir and Nebulizer Adaptor Configurations:** Class IIb, Rule 11 |
| **EC Certificates No.:** | **Canadian** – MDSAP (ISO 13485:2016) – US18/81827522<br>**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***


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|---|---|
| **Name and Title of Approver:** | Nicole Schaffer<br>Regulatory Affairs Manager, Respiratory |
| **Signature of Approver:** |  |
| **Date Approved:** | 27 Apr 2021 |
| **Site Where Approved:** | Teleflex Medical<br>3015 Carrington Mill Blvd<br>Morrisville, NC 27709<br>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 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**<br><br>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**<br><br>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**<br><br>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 | | |

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| | | | |
|---|---|---|---|
| 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>**<br>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.<br><br>**<u>Nebulizers:</u>**<br>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 |


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| | 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<br>**Arlington Heights**, IL 60004<br>USA |
| Teleflex Medical de Mexico, S. de R.L. de C.V. | Ave. Industrias No 5954<br>Parque Industrial Finsa<br>**Nuevo Laredo**, Tamaulipas, 88275<br>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<br>Gurnee, IL 60031<br>USA<br>*Gamma irradiation for individually sold nebulizer adaptors*<br><br>711 E. Cooper Court<br>Schaumburg, IL 60173<br>USA<br>*Gamma irradiation for humidifier adaptors (individually sold and kitted) and kitted nebulizer adaptors* |
| Teleflex Medical | 900 W. University Drive<br>**Arlington Heights**, IL 60004<br>USA<br>*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<br>EN ISO 13485 | Medical devices - quality management systems - requirements for regulatory purposes | 2016<br>2016 |
| EN ISO 14971 | Medical devices - application of risk management to medical devices | 2012 |


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| | | |
|---|---|---|
| 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 | |

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