EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	*Teleflex Medical* *3015 Carrington Mill Boulevard* *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 II (excluding Section 4) and *EN ISO 13485:2016,* 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 II (excluding Section 4) 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:	CPAP Cannula System
Classification:	EU Classification: Class IIa - Rule 5 Canadian Classification: Class 2
EC Certificates No.:	Canadian – MDSAP (ISO 13485:2016) – US18/81827522 European – ISO 13485:2016, EN ISO 13485:2016 – US97/10878.00 Directive 93/42/EEC –US19/819943647.00 (CE 1639)

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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
41683	Infant Nasal CPAP Cannula System Size 0	September 6, 2005	35202
41685	Infant Nasal CPAP Cannula System Size 1	September 6, 2005	35202
41686	Infant Nasal CPAP Cannula System Size 2	September 6, 2005	35202
41687	Infant Nasal CPAP Cannula System Size 3	September 6, 2005	35202
41688	Infant Nasal CPAP Cannula System Size 4	September 6, 2005	35202
41689	Infant Nasal CPAP Cannula System Size 5	September 6, 2005	35202
41690	Infant Nasal CPAP Cannula Set Size 0	September 6, 2005	35202
41691	Infant Nasal CPAP Cannula Set Size 1	September 6, 2005	35202
41692	Infant Nasal CPAP Cannula Set Size 2	September 6, 2005	35202
41693	Infant Nasal CPAP Cannula Set Size 3	September 6, 2005	35202
41694	Infant Nasal CPAP Cannula Set Size 4	September 6, 2005	35202
41695	Infant Nasal CPAP Cannula Set Size 5	September 6, 2005	35202

**** 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:	01 Apr 2021
Site Where Approved:	*Teleflex Medical, Inc.* *3015 Carrington Mill Blvd.* *Morrisville, NC 27560* *USA*

Classification Justification

Nasal cannulas are used to deliver oxygen to the patient through the nasal passage (Devices invasive with respect to body orifices) Rule 5.

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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
1683	Infant Nasal CPAP Cannula System Size 0	7582	2004-08-26	2
1685	Infant Nasal CPAP Cannula System Size 1	7582	2003-01-02	2
1686	Infant Nasal CPAP Cannula System Size 2	7582	2003-01-02	2
1687	Infant Nasal CPAP Cannula System Size 3	7582	2003-01-02	2
1688	Infant Nasal CPAP Cannula System Size 4	7582	2003-01-02	2
1689	Infant Nasal CPAP Cannula System Size 5	7582	2003-01-02	2
1690	Infant Nasal CPAP Cannula Set Size 0	7582	2003-01-02	2
1691	Infant Nasal CPAP Cannula Set Size 1	7582	2003-01-02	2
1692	Infant Nasal CPAP Cannula Set Size 2	7582	2003-01-02	2
1693	Infant Nasal CPAP Cannula Set Size 3	7582	2003-01-02	2
1694	Infant Nasal CPAP Cannula Set Size 4	7582	2003-01-02	2
1695	Infant Nasal CPAP Cannula Set Size 5	7582	2003-01-02	2

Product Description	The infant nasal CPAP are used to provide continuous positive airway pressure or (CPAP).
Indications for Use	The infant nasal CPAP Cannula System is indicated for administration of continuous positive airway pressure (CPAP) therapy to neonates and infants.
Intended Use	The infant nasal CPAP is used for providing continuous positive airway pressure (CPAP) therapy to neonates and infants.
Contraindications	There are no contraindications for these devices.
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.

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Sterilization Site Name	Sterilization Site Address
N/A	N/A

Standards

The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Name	Standard Issue Date
93/42/EEC MDD	Medical Device Directive as amended by 2007/47/EC	2007
ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2003
EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2012
21CFR Part 820	Quality System Regulation	2011
ISO 14971 BS EN ISO 14971	Medical devices – Application of risk management to medical devices	2012 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
BS EN ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	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
EN 980	Symbols for use in the labeling of medical devices	2008
EN 1041+A1:2013	Information supplied by the manufacturer of medical devices	2013
21 CFR Part 801	Labeling	2011
CMDR	Canada Medical Device Regulations	
ISO 5356-1	Anesthetic and Respiratory Equipment - Conical Connectors – Part 1: Cones and Sockets	2004
EU MEDDEV 2.7.1	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies	2009
ISTA 1A	Non-simulation integrity performance test procedure	

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