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 CE1639*

☐ **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, and 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, and 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:	Non-Sterile Respiratory and Anaesthesia Masks
Classification:	European Class IIa Rule 2; Canadian Class II Rule 5

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EC Certificates No.:	Canadian – ISO 13485:2016-US18/81827522 European – EN ISO 13485:2016-US97/10878.00, Directive 93/42/EEC- 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 Code
OXYGEN MASKS			
Low Flow			
41035	MASK,MED CONC,PED,INTL	September 6, 2005	35171
41040	MASK,MED CONC,ADULT,INTL	September 6, 2005	35171
1041	MASK,MEDIUM CONC,ELONG,ADULT	September 6, 2005	35171
1041L	MASK,MEDIUM CONCEN,ADULT ELONGATED	September 6, 2005	35171
1041B	MASK,MEDIUM CONC,ELONG,ADULT,BULK	September 6, 2005	35171
41042	MASK,MED CONC,ELONG,PED,INTL	September 6, 2005	35171
1049	MASK,MEDIUM CONC W/O TUBING,ELONG,ADULT	September 6, 2005	35171
1049B	MASK,1049 ADULT (BULK)	September 6, 2005	35171
41050	MASK,MED CONC,ELONG W/O TBG,PED,INTL	September 6, 2005	35171
41007	MASK,HIGH CONC,ADULT,INTL	September 6, 2005	35174
395406	INFANT MASK REBRTH HIGH C	September 6, 2005	35174
395497	INFANT OXY HI-CON	September 6, 2005	35174
395498	Infant Mask Non-Rebth High ConC 50/BOX	September 6, 2005	35173
395407	INFANT OXY HI-CON	September 6, 2005	35174
395499	INFANT MASK MEDIUM CONCEN	September 6, 2005	35171
396218	INFANT MSK MED CONCT 7' T	September 6, 2005	35171
395826	INFANT MASK UNDER THE CHIN	September 6, 2005	35171
41058	MASK,NON-REBREATHING W/SAFETY VENT,ELO	September 6, 2005	35173
41058L	MASK,NON-REBREATH,W/SFTY VENT,PED ELONG	September 6, 2005	35173
1059	MASK,NON-REBREATH W/SAFETY VENT,ELONGATE	September 6, 2005	35173
1059L	MASK,NON-REBREATHING,W/SAFETY VENT,ADULT	September 6, 2005	35173

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41060	MASK,NON-REBREATING W/O SFTY VENT,ELONG	September 6, 2005	35173
41069	MASK,NON-REBREATH W/SAFETY VENT,ELONG	September 6, 2005	35173
41061	MASK,THREE-IN-ONE,W/7' TUBING,INTL	September 6, 2005	35174
41063	MASK,THREE-IN-ONE,W/7' STAR LUMEN TUBING	September 6, 2005	35174
1389	OXYME FACE TENT	June 2008	35171
High Flow – Multi-Vent			
41088	MASK,MULTI-VENT,ADULT,INTL	September 6, 2005	35175
41089	MASK,MULTI-VENT,PEDIATRIC,INTL	September 6, 2005	35175
High Flow – Select-A-Vent			
41098	MASK KIT,FIXED VENTURI,ADULT,INTL	September 6, 2005	35175
41072	SELECT-A-VENT FIXED DILUTER AIR ENTRAINM	September 6, 2005	35175
AEROSOL MASKS			
1083	MASK,AEROSOL,ELONGATED,ADULT	September 6, 2005	35142
1083B	MASK,AEROSOL,ELONGATED,ADULT (Bulk)	September 6, 2005	35142
41085	MASK,AEROSOL,ELONG,PED,INTL	September 6, 2005	35142
41095	FACE TENT,INTL	September 6, 2005	35142
1075	MASK,TRACHEOSTOMY,ADULT	September 6, 2005	35142
41076	MASK, TRACHEOSTOMY, PED, INTL	September 6, 2005	35142

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

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The following devices meet Canadian requirements as listed:

Product Code	Product Description	Canadian License #	Issue Date	Class of Product
41035	MASK,MED CONC,PED,INTL	7354	10-15-2012	2
41040	MASK,MED CONC,ADULT,INTL	7354	10-15-2012	2
1041	MASK,MEDIUM CONC,ELONG,ADULT	7354	7-7-1999	2
41042	MASK,MED CONC,ELONG,PED,INTL	7354	10-15-2012	2
1049	MASK,MEDIUM CONC W/O TUBING, ELONG, ADULT	7354	7-7-1999	2
41050	MASK,MED CONC,ELONG W/O TBG, PED, INTL	7354	10-15-2012	2
41007	MASK,HIGH CONC,ADULT,INTL	7354	9-27-2012	2
395406	INFANT MASK REBRTH HIGH C	8723	1-22-2009	2
395497	INFANT OXY HI-CON	8723	1-22-2009	2
395498	Infant Mask Non-Rebth High ConC 50/BOX	8723	1-22-2009	2
395407	INFANT OXY HI-CON	8723	1-22-2009	2
395499	INFANT MASK MEDIUM CONCEN	89053*	6-15-2012	2
395826	INFANT MASK UNDER THE CHIN	89053*	6-15-2012	2
396218	INFANT MSK MED CONCT 7' T	89370*	7-26-2012	2
41058	MASK,NON-REBREATHING W/SAFETY VENT,ELONG	7585	10-15-2012	2
1059	MASK,NON-REBREATH W/SAFETY VENT,ELONGATE	7585	7-9-1999	2
41060	MASK,NON-REBREATING W/O SFTY VENT,ELONG	7585	10-15-2012	2
41069	MASK,NON-REBREATH W/SAFETY VENT,ELONG	7585	10-15-2012	2
41061	MASK,THREE-IN-ONE,W/7' TUBING,INTL	7354	10-15-2012	2
41063	MASK,THREE-IN-ONE,W/7' STAR LUMEN TUBING	7354	10-15-2012	2
41088	MASK,MULTI-VENT,ADULT,INTL	7354	10-15-2012	2
41089	MASK,MULTI-VENT,PEDIATRIC,INTL	7354	10-15-2012	2
41098	MASK KIT,FIXED VENTURI,ADULT,INTL	7354	10-15-2012	2
1083	MASK,AEROSOL,ELONGATED,ADULT	7354	7-7-1999	2

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41085	MASK,AEROSOL,ELONG,PED,INTL	7354	10-15-2012	2
41095	FACE TENT,INTL	7354	10-15-2012	2
1389	OXYME FACE TENT	7354	3-31-2008	2
1075	MASK,TRACHEOSTOMY,ADULT	7354	7-7-1999	2
41076	MASK, TRACHEOSTOMY, PED, INTL	7354	10-15-2012	2

*Indicates Canadian Private Label License for the Purchased Finished Good

Product Description	**<u>Aerosol Masks:</u>** Aerosol masks are used to surround the patient's nose and mouth or surgical airway and deliver aerosol therapy for inhalation. Types of aerosol masks include standard and elongated face masks, tracheostomy masks, and face tents. The tracheostomy mask is a specialized aerosol mask that provides the user with a tubing connector that swivels 360 degrees while being used for laryngectomy aerosol therapy. The face tent is an open mask that fits around the chin, designed for patients with facial trauma or who cannot tolerate a full face mask for aerosol delivery. The devices in this family are manufactured with soft PVC materials for comfort and flexibility. All devices are disposable, non-sterile, single use, and not for reprocessing. **<u>Oxygen Masks:</u>** Oxygen masks are used to surround the patient's nose and mouth and deliver a greater than ambient concentration of oxygen. Types of oxygen masks include air entrainment, medium concentration, high concentration, rebreathing, and non-rebreathing masks, each of which provides a specific range of delivered flows and oxygen concentrations. • *Low-flow oxygen masks* provide oxygen at less than the minimum peak inspiratory flow rate required by the patient. The additional required flow is provided by the entrainment of room air through holes in the mask, the gas reservoir provided by the mask's volume, and an additional gas reservoir (bag) or some combination of the three. *High-flow (or air entrainment) oxygen masks* provide more oxygen to the patient than required at the peak inspiratory

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	flow rate. These masks use a venturi device to mix large volumes of air from the surrounding environment with pressurized oxygen to provide a precise oxygen concentration. They use either an adjustable venturi device or multiple venturi devices to permit a precise control of the oxygen concentration.
Indications for Use	**Oxygen Masks:** Oxygen masks are single use devices that fit over the nose and mouth of a patient and are intended to supplement or enrich the air supply with medical oxygen. **Aerosol Masks:** Aerosol masks are single use devices that fit over the nose and mouth of a patient and are intended to deliver aerosol therapy to the patient for inhalation of nebulized medications or for humidification of the respiratory tract.
Intended Use	**Oxygen Masks:** Oxygen masks are single use devices that fit over the nose and mouth of a patient and are intended to supplement or enrich the air supply with medical oxygen. **Aerosol Masks:** Aerosol masks are single use devices that fit over the nose and mouth of a patient and are intended to deliver aerosol therapy to the patient for inhalation of nebulized medications or for humidification of the respiratory tract.
Contraindications	There are no contraindications for these devices.
Manufacturing Site(s)	

Manufacturing Site Name	Manufacturing Site Address	Product Codes manufactured:
Foremount Enterprise Co., Ltd.	No. 17, Alley 17, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan	396218, 395826, 395499
Teleflex Medical De Mexico S. De R.L. De C.V.	Ave. Industrias No 5954 Parque Industrial Finsa, Nuevo Laredo, MEXICO 88275	All other codes

Sterilizer	☒ N/A: The product is sold non-sterile.

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☐ The product is sold sterile.

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

Standards

The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Issue Date	Standard Name
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	2016
EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2016
21CFR Part 820	Quality System Regulation	
BS 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: 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 1041+A1:2013	Information supplied by the manufacturer of medical devices	2013
21 CFR Part 801	Labeling	
CMDR	Canada Medical Device Regulations	
ISO 5356-1	Anesthetic and Respiratory Equipment - Conical Connectors – Part 1: Cones and Sockets	2015
EU MEDDEV 2.7.1	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies	2009
ISTA 1A	Non-stimulation integrity performance test procedure.	

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