EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Blvd Morrisville, NC 27560 USA
Authorized Representative Name and Address:	TFX Medical Ltd. 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 of the MDD (93/42/EEC), and EN ISO 13485:2012, 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:	**Incentive Spirometers**
Classification:	**Class 1, Rule 5 (measuring) (EU)** **Class 2, Rule 5 (CA)**
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 – US19/819943645**

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Conformity Assessment Routes:	**Annex VII of the MDD (93/42/EEC), EC Declaration of Conformity** **Annex V of the MDD (93/42/EEC), Production Quality Assurance**

Product Code	Product Description	CE Distribution Date	GMDN Code
8884719033	Voldyne 5000 Volumetric Exerciser	6 September 2005	31266
8884719041	Voldyne 2500 Volumetric Exerciser	6 September 2005	31266
8884719040	Voldyne 2500 Pediatric Volumetric Exerciser	14 July 2015	31266
8884717395	Triflo II Respiratory Exerciser	6 September 2005	31266
41750	Incentive Spirometer	6 September 2005	31266
8884719015	Voldyne 2500 Pediatric Volumetric Exerciser - CE Marked	13 April 2021	31266
8884719016	Voldyne 4000 Volumetric Exerciser - CE Marked	13 April 2021	31266
8884719018	Voldyne 2500 Volumetric Exerciser - CE Marked	13 April 2021	31266

**** 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 Manager, Regulatory Affairs
Signature of Approver:	Nicole Schaffer
Date Approved:	13 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 incentive spirometer family. The rationale for classification is provided:

Class I Products:

Product Codes:	Product Description	Rule	Rationale
8884719033	Voldyne 5000 Volumetric Exerciser	Rule 5	"Incentive Spirometers indicate a patient's breathing volume or flow and intended for transient use (All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device) Rule 5.".
8884719041	Voldyne 2500 Volumetric Exerciser		
8884719040	Voldyne 2500 Pediatric Volumetric Exerciser		
8884717395	Triflo II Respiratory Exerciser		
41750	Incentive Spirometer		
8884719015	Voldyne 2500 Pediatric Volumetric Exerciser - CE Marked		
8884719016	Voldyne 4000 Volumetric Exerciser - CE Marked		
8884719018	Voldyne 2500 Volumetric Exerciser - CE Marked		

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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
8884719033	Voldyne 5000 Volumetric Exerciser	20954	5/31/2000	2
8884719041	Voldyne 2500 Volumetric Exerciser	20954	5/31/2000	2
8884717395	Triflo II Respiratory Exerciser	20954	5/31/2000	2
41750	Incentive Spirometer	20954	2/14/2003	2
8884719015	Voldyne 2500 Pediatric Volumetric Exerciser - CE Marked	TBD	TBD	2
8884719016	Voldyne 4000 Volumetric Exerciser - CE Marked	TBD	TBD	2
8884719018	Voldyne 2500 Volumetric Exerciser - CE Marked	TBD	TBD	2

Product Description	**Voldyne (8884719033, 8884719041, 8884719040)** This device is made of a clear polystyrene material to visualize the rise of the piston inside when the patient inhales air. It is marked with a graduation from 500 ml to 5,000 ml or 500 ml to 2,500 ml on the front and the back of the main chamber. Also it is marked in the front with the "Hudson RCI" logo and the "Voldyne 5000" or "Voldyne 2500" trade mark. Depending on the version, the flow cup chamber is marked with the "Good, Better, Best". The device has two chambers, one for the flow cup and one for the piston. The flow cup will rise at the same time the piston is raised; the flow on both chambers is split at the tube port. It also includes an adjustable external pointer which can be set at the goal to be achieved in the prescribed therapeutic exercise. The device has a patient label at the bottom that helps to maintain the piston in place when the device is standing still. It has a tube port, where the corrugated tubing is attached, and also has a mouthpiece that is attached to the corrugated tubing. Most of the models have a filter built in the mouthpiece to reduce the risk of foreign matter to pass to the patient. The pediatric version uses a smaller mouthpiece; therefore the filter is not in the mouthpiece, however is attached to the tube port and is made out of a stainless steel mesh. The Voldyne volumetric exercisers are volumetric incentive spirometers. They are for therapeutic use as an inspiratory deep breathing exerciser and are not intended for any diagnostic purpose. It is supplied in clean, sanitary condition, ready for use. It is designed for single patient use. That it is to be used by only one patient and then discarded when no longer needed by the patient to whom assigned. By indicating breathing volume and flow it provides an exercise incentive to patients who require sustained maximal inspiration (SMI), or similar maneuvers, to improve their ventilation.

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Voldyne (8884719015, 8884719016, 8884719018)

The Voldyne is made of a clear polystyrene material which allows the patient to visualize the rise of a flow chip and piston inside the device when the patient inhales air through the mouth piece. The piston chamber is marked with a graduation from 500 ml to 4,000 ml (for the Voldyne 4000) or 250 ml to 2,500 ml (for the Voldyne 2500 and Voldyne Pediatric) on the front and the back of the main housing. The flow chip chamber for the device is marked with a happy face symbol with arrows pointing to the optimum position of the flow chip. The Voldyne Pediatric version includes a sticker sheet with clouds and trees graphics, which can be placed onto the device for decoration.

When the patient inhales the flow chip and piston rise due to the negative pressure created; this indicates breathing volume and flow, while the device provides an exercise incentive to patients who require sustained maximal inspiration (SMI).

Triflo II (8884717395)

This device is made of a clear polystyrene material to visualize the movement of the balls inside the three chambers when the patient inhales air. Each one of the chambers is marked with 600 cc, 900 cc and 1200 cc on the front of the device.

The device has three chambers, each one of them contains a ball with a different color. The device has a patient label at the bottom. A filter on the tube port is present which reduces the risk of foreign matter passing to the patient. It has a tube port, where the corrugated tubing is attached, and also has a mouthpiece that is attached to the corrugated tubing.
The Triflo II is an incentive spirometer. The device is a non-diagnostic, therapeutic inspirometer (inspiratory deep-breathing exerciser) designed for a maximum flow rate of approximately 1200 cc/sec. It is supplied in clean, sanitary condition, ready for use. It is designed for single patient use, that is it's to be used by only one patient and then discarded when no longer needed by the patient to whom assigned. By sequentially lifting the balls that are inside every chamber it provides an exercise incentive to patients who require sustained maximal inspiration (SMI), or similar maneuvers, to improve their ventilation.

The Triflo II is a flow-orientated spirometer which provides an indirect indicator of the patient's inspired volume. The tube is calibrated so displacement is equal to specific flow in cc/sec or mL/sec, as indicated on the wall of the tube. Inspired volume is estimated by multiplying the inspired flow times the number of seconds the ball remains elevated. Because of the lack of precision with flow-orientated spirometers, measurements are treated as rough estimates of the actual inspired volume.

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	Incentive Spirometer (41750) The Lung Volume Exerciser is a device that helps exercise recovering patient's lungs by encouraging sustained maximal inspiration. The device allows patient to time inhalation as compared to previous breaths by using negative air pressure to float a plastic ball of known weight within the cylinder.
Indications for Use	An Incentive Spirometer is a device most commonly used post-surgery to encourage deep breathing and coughing, to exercise respiratory musculature, and to prevent atelectasis (collapsed air sacs in the lungs). The Hudson RCI® Voldyne® Volumetric Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 yrs) patients. It is a single patient, multi-use device used in hospital or home care setting.
Intended Use	An Incentive Spirometer is a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation
Contraindications	These products do not list any contraindications on the labeling.
Manufacturing Site(s)	

Manufacturing Site Name	Manufacturing Site Address
Manufacturing Facility for 8884719033, 8884719040, 8884719041	Hudson Respiratory Care Tecate S. de R.L., Teleflex Medical Company Prol. Mision Eusebio Quino # 1316, Rancho el Descanso CP, Tecate, 21478 Mexico
Manufacturing Facility for 41750, 8884717395, 8884719015, 8884719016, 8884719018	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

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Standards
The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Issue Date	Standard Name
ISO 13485	2016	Medical devices - quality management systems - requirements for regulatory purposes
EN ISO 13485	2016	Medical devices - quality management systems - requirements for regulatory purposes
EN ISO 14971	2012	Medical devices - application of risk management to medical devices
EN ISO 10993-1	2009	Biological evaluation of medical devices part 1: evaluation and testing within a risk management process
EN ISO 10993-5	2009	Biological evaluation of medical devices part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-10	2013	Biological evaluation of medical devices part 10: Test for irritation and skin sensitization.
ISO 15223-1	2016	Medical devices - symbols to be used with medical device labels, labeling and information to be supplied - part 1: general requirements
93/42/EEC MDD	2007	Medical Device Directive as amended by 2007/47/EC
21CFR Part 820	2011	Quality System Regulation
CMDR		Canadian Medical Device Regulations
EN 1041 + A1	2013	Information Supplied by the Manufacturer of Medical Devices
ISO 5356-1	2015	Anesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
MEDDEV 2.7.1 Rev 4	2016	Clinical Evaluation: Guide for Manufacturers and Notified Bodies

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