EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102880
Revision v 00

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device(s)/accessories covered by this Declaration are in conformity with all regulations or directives below.

1. Object of the declaration:

Product Name:	InnoSpire Go
Product Type:	Nebulizer
Intended Purpose:	The Innospire Go is a general purpose mesh nebulizer that is intended to be used to nebulize commonly prescribed liquid inhaled medications for respiratory disease. It is intended for single patient use, to deliver multiple doses.
Product Part Number(s) and Descriptions:	Part Number / Description 1126560 – InnoSpire Go Europe2 ROW 1126584 – InnoSpire Go UK INT 1126591 – InnoSpire Go Americas/Japan 1126593 – InnoSpire Go EUROPE1/ ROW 1135360 – InnoSpire Go AU/NZ
Product Options/Accessories Part Number(s) and Descriptions:	Part Number / Description 1125985 – InnoSpire Go Mask Adapter 1127798 – InnoSpire Go LiteTouch medium mask 1127822 – InnoSpire Go LiteTouch small mask 1127875 – InnoSpire Go Litetouch large mask 1128501 – InnoSpire Go Mouthpiece Assembly
Basic UDI-DI:	NA
Control Indicator:	Initial Issue Date / Part Number Nov-2016 – 1126560 Nov-2016 – 1126584 Nov-2016 – 1126591 Nov-2016 – 1126593 Nov-2016 – 1135360
Global Medical Device Nomenclature Code (GMDN) and Description:	12719 – Ultrasonic nebulizing system

The object of the declaration described above is in conformity with the following directives and/or regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)**
Device Risk Classification	Class IIa based on Annex IX and Rule 11
Conformity Assessment Route	Annex II (without section 4) of the Medical Device Directive 93/42/EEC.
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstrasse 65 - 80339, Műnchen, Germany 0123
Certificate(s) Issued	EC certificate number - G1 062364 0042
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A.

EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/1202 (RoHS)**
Device Risk Classification	Category 8, medical device, according Annex I
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A

2. Additional information:

Manufacturer	Respironics Respiratory Drug Delivery (UK) Ltd Chichester Business Park, City Fields Way, Tangmere, Chichester, West Sussex PO20 2FT UNITED KINGDOM
EU Authorized Representative:	Philips Medical Systems Nederland B.V.

EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102880
Revision v 00

	Veenpluis 6 5684PC Best The Netherlands
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485:2016 certificate number: Q5 062364 0041 ISO 13485:2016 MDSAP Certificate Number: QS6 062364 0038

Signature (signed for and on behalf of Respironics Respiratory Drug Delivery (UK) Ltd):

Daria Brown

Date of Issue: 15-DEC-2020

15 Dec 2020

Printed Name:
Daria Brown

Title:
Senior Manager, Regulatory Affairs

Place of Issue:
Monroeville, PA
United States of America

3. Attachment A

Standards and/or Common Specifications

Standard	Standard Title
Quality System	
EN ISO 13485:2016	Medical devices -Quality management systems. Requirements for regulatory purposes
General Safety Standard	
EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
Collateral Safety Standard	
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 +A1:2015	Medical electrical equipment – Part 6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-1-11:2015	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Particular Safety Standards	
Nebulizers	
EN 13544-1:2007+A1:2009	Respiratory Therapy Equipment Part I. Nebulizing systems and their Components.

Doc Number REG 2102880
Revision v 00

Standard	Standard Title
Biocompatibility	
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices-part 5: Tests for local effects after implantation
EN ISO 10993-11:2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-17:2009	Biological evaluation of medical devices- Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices- Part 18: Chemical characterisation of materials
Other Standards	
Accompany Documents and Labeling	
EN 1041:2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
Risk Management	
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.
Usability	
EN 62366:2008+A1:2015	Medical Devices – Application of Usability Engineering to Medical Devices
Software	
EN 62304: 2006/ AC:2008	Medical Device Software- Software Lifecycle Process
ROHS	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances