EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102272
Revision 02

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:	Whisper Swivel II
Product Type:	Circuit Accessories
Intended Purpose:	The Whisper Swivel II is a multi-patient use exhalation port that provides a continuous leak path in the patient circuit when used with positive pressure devices.
Product Part Number(s) and Descriptions:	332113 Whisper Swivel II
Product Options/Accessories Part Number(s) and Descriptions:	None
Basic UDI-DI:	NA
Control Indicator:	Initial Issue Date Part Numbers November 14, 2006 332113
Global Medical Device Nomenclature code (GMDN) and Description	42601 Tube/mask breathing circuit connector, reusable

The object of the Declaration (product part numbers and if applicable the component part numbers) that are described above as included in this DoC is / are in conformity with the following regulations / directives. If optional accessories that are used in combination with the product (medical device), but are CE marked on their own are referenced in this DoC, they are excluded further on as these optional accessories have their own DoC.

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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)
Risk Classification	Class IIa based on Annex IX and Rule 2
Conformity Assessment Route	Annex II
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrase 65 80339 Munich, Germany 0123
Certificate(s) Issued	EC Certificate: G1 015581 0611
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. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA
EU Authorized Representative (AR):	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485 and Annex II-Section 3.2 of the MDD as evidenced by certificate numbers EN ISO 13485 Certificate: Q5 015581 0609 MDSAP ISO 13485 Certificate: QS6 015581 0610

Signature (signed for and on behalf of Respironics, Inc)

Date of Issue: 01 June 2021

Place of Issue: Monroeville, PA, USA

Printed Name: Daniela Zaczek

Title: Sr. Manager Regulatory Affairs

3. Attachment A Standards and/or Common Specifications

Quality System	
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Safety Standards	
Patient Interface	
EN ISO 17510:2015	Medical devices – Sleep apnoea breathing therapy – Masks and application accessories
Biocompatibility	
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
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 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-17:2009	Biological evaluation of medical devices. Part 17: Establishment of allowable limits for leachable substances
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
Other Standards	
Accompany Documents and Labeling	
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
EN 1041: 2008/A1: 2013	Information supplied by the manufacturer of medical devices
Risk Management	
ISO 14971:2019	Medical devices – Application of risk management to medical devices
Usability	
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
Connectors	
ISO 5356-1: 2015	Anaesthetic and respiratory equipment — Conical connectors —Part 1: Cones and sockets