EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number 2102865
Revision v03

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:	Sami the Seal
Product Type:	Compressor
Intended Purpose:	This is an AC-powered air nebulizer compressor system intended to provide a source of compressed air for medical purposes. It is to be used with a pneumatic nebulizer to produce aerosol particles of medication for respiratory therapy for both children and adults.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directive(s) indicated in DoC unless otherwise noted. The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC, Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electric and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS) in Electric and Electronic Equipment (EEE):

Part Number	*Description*
1093235	Sami the Seal 220V/60Hz (US Plug)
1093268	Sami the Seal 230V/ 50Hz (EU Plug)
1093270	Sami the Seal 230V/ 60Hz (UK Plug)
1119462	Sami the Seal
1136955	Sami the Seal 230V/ 50Hz (Argentina)

Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 2102870 for SideStream Disposable and REG 2102872 for SideStream Reusable.
Basic UDI-DI:	Not Applicable
Control Indicator:	

Initial Issue Date:	Part Number:
04-May- 2012	1093235
04-May- 2012	1093268
04-May- 2012	1093270
04-May- 2012	1119462
04-May- 2012	1136955

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Global Medical Device Nomenclature code (GMDN) and Description	35457 – Nebulizing system, non-heated

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.

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 11
Conformity Assessment Route	Annex II excluding (4)
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 2015/863 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) 2017/2102**
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

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2. Mandatory 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 (AR):	Philips Medical Systems Nederland B.V. 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

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

Daria Brown

Date of Issue: 12-May-2022

12 MAY 2022

Printed Name:
Daria Brown

Place of Issue: Pittsburgh, PA
United States of America

Title:
Senior Manager, Regulatory Affairs

This declaration is valid until: 26-May-2024

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.
Biocompatibility	
EN ISO 10993-1:2020	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: Tests for irritation and skin sensitization
EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
EN ISO 18562-2:2020	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 2: Tests for Emissions of Particulate Matter
EN ISO 18562-3:2020	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 3: Tests for Emissions of Volatile Organic Compounds
EN ISO 18562-4:2020	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 4: Tests for Leachables in Condensate
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 62366-1:2015/ AC:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
ROHS	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances