EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102380
Revision v02

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:	CoughAssist E70 Accessories
Product Type:	Mechanical Positive Pressure Airway Secretion Clearing Device Accessories
Intended Purpose:	Circuits and circuit accessories: An assembly of devices designed to conduct air or oxygen (O2) enriched gases and additional gases [e.g., nitrous oxide (N2O), halogenated gases] from a ventilator to a patient. It includes breathing tubes, a Y-piece connector, and provides connections for devices that humidify, deliver medication, and monitor gas concentration or pressure within the breathing circuit; some types may include an integrated heating wire powered by a connected humidifier intended to warm breathing gases as they enter the patient's airway. This is a single-use device. Water Trap: Device intended to trap and drain water and respiratory secretions from a patient that collect in the circuit tubing during respiratory therapy, thereby preventing an increase in breathing resistance. Pulse Oximetry Interface Kit: A small unit dedicated to the transcutaneous measurement of haemoglobin oxygen saturation (SpO2) in blood using light detection methods (spectrophotometry) after light is emitted from a light-emitting diode (LED) situated in the connected probe. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). The module automatically plugs into the parent device when the user places it into a standardized slot in the parent device or a connected module rack. The parent device operates as a mainframe computer displaying the pulse oximetry parameters provided by this module.
Product Part Number(s) and Descriptions:	The following Finished Goods are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC: 325-9237 Patient Circuit, CA Infant

	325-9236 Patient Circuit, CA Toddler 325-9235 Patient Circuit, CA Small 325-9234 Patient Circuit, CA Medium 325-9217 Facemask,Adult,Lg,W/Hose,Filter,Adapter 325-9238 Patient Circuit, CA Trach 325-9239 Mouth Piece W/ Breathing Hose And Filter 1090830 CoughAssist 70 Series Circuit, Infant, 6ft 1090831 CoughAssist 70 Series Circuit, Toddler, 6ft 1090832 CoughAssist 70 Series Circuit, Adult, Small 6ft 1090833 CoughAssist 70 Series Circuit, Adult, Medium, 6ft 1090834 CoughAssist 70 Series Circuit, Adult Large, 6ft 1090835 CoughAssist 70 Series Circuit, Trach, 6ft 1090836 CoughAssist 70 Series Circuit, Mouthpiece, 6ft 1098403 CoughAssist 70 Series Circuit, Infant, 9ft 1098404 CoughAssist 70 Series Circuit, Toddler, 9ft 1098405 CoughAssist 70 Series Circuit, Adult, Small, 9ft 1098407 CoughAssist 70 Series Circuit, Adult, Medium, 9ft 1098408 CoughAssist 70 Series Circuit, Adult, Large, 9ft 1098409 CoughAssist 70 Series Circuit, Trach, 9ft 1098410 CoughAssist 70 Series Circuit, Mouthpiece, 9ft 1044186 CoughAssist, Adpater, 22mm x 22mm 1044191 CoughAssist, Adapter, 22mm x 15mm 1044428 Smooth Bore Tube, 22mm X 36” 1044821 CoughAssist Mouthpiece Rigid 1098720 CA70 Series, Water Trap 1099533 CA70 Series Mouthpiece 1116178 CA70, 6FT Clear Tube The following Finished Goods are compliant with 2011/65/EU Restriction of the use of certain Hazardous Substances (R0HS) in Electric and Electronic Equipment (EEE) and 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC: 1098718 CA E70 Series Oximetry Interface Kit
Product Options/Accessories Part Number(s) and Descriptions:	Accessories to the CoughAssist E70 Device Note: CoughAssist E70 Declaration of Conformity - REG 2101253
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: Part Number: 8/5/2012 1098720 3/14/2014 1044186, 1044428

	10/21/2016 11/8/2017 01/05/2021	1090830, 1090831, 1090832, 1090833, 1090834, 1090835, 1090836, 1098403, 1098404, 1098405, 1098407, 1098408, 1098409, 1098410, 1044191, 1044821, 1099533, 1116178 1098718 325-9237, 325-9236, 325-9235, 325-9234, 325-9217, 325-9238, 325-9239
Global Medical Device Nomenclature code (GMDN) and Description	37706 Ventilator breathing circuit, single-use 61346 Tube/mask breathing circuit connector, non-sterile, single-use 46232 Anaesthesia face mask, single-use 44545 Breathing Mouthpiece, Single-Use 60837 Microbial medical gas filter, non-sterile, single-use 41679 Breathing circuit condensate trap, single-use 36554 Patient monitoring system module, pulse oximetry	

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)**
Risk Classification	Class IIa, Annex IX, Rule 2 Class IIa, Annex IX, Rule 10 (1098718)
Conformity Assessment Route	Annex II, excluding 4
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123
Certificate(s) Issued	EC Certificate: G1 015581 0608
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. Additional information:

Manufacturer	Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668, USA
EU Authorized Representative:	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 Certificate: Q5 015581 0607 MDSAP ISO 13485 Certificate: QS6 015581 0610
Supplementary Information	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

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

Daria Brown

Date of Issue: 06 JANUARY 2021

06 JAN 2021

Printed Name:
Daria Brown

Place of Issue: Monroeville, PA, USA

Title: Senior Regulatory Manager

REG 2102380

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 Standards	
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 1-6: General requirements for 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	
Biocompatibility	
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Pulse Oximetry	
EN ISO 80601-2-61:2011	Medical electrical equipment. Particular requirements for basic safety and essential performance of pulse oximeter equipment
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
Software	
EN 62304:2006/A1:2015	Medical device software – Software lifecycle processes
Risk Management	
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
Usability	
EN 62366-1:2015	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