EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101253
Revision v22

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 ATOS 70 Easy Cough
Product Type:	Mechanical Insufflation/Exsufflator
Intended Purpose:	The Respironics CoughAssist E70 device promotes airway clearance by gradually applying air pulse generated high frequency oscillatory vibrations on the positive and negative pressures applied to the chest wall via the airways. The high frequency oscillatory vibrations release mucus from the bronchial walls, increasing mobilization. The shift in pressure produces a high expiratory flow from the lungs, promoting the clearance of the mobilized secretions via coughing. The Respironics CoughAssist E70 device may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. It is for use on adult or pediatric patients having difficulty with secretion clearance and/or inability to cough. The CoughAssist E70 device is for use in a hospital, institutional environment or in the home. The External Battery Cable provides for safe connection to a standard deep-cycle, lead acid battery to the Trilogy Series of Ventilators. The Auto DC Cable Adaptor provides for a safe connection to a standard automotive electrical system to the Trilogy Series of Ventilators.
Product Part Number(s) and Descriptions:	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 2011/65/EU 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) 2017/1202 (RoHS) in Electric and Electronic Equipment (EEE):

	1098159 CoughAssist E70, International 1098163 CoughAssist E70, Japan 1098161 CoughAssist E70, Brazil 1098162 CoughAssist E70, China 1138050 CA E70, Russia 1125426 ATOS 70 1130729 EasyCough IT1098159 CoughAssist E70 International, IT FR1098159 CoughAssist E70 FR 1140677 CoughAssist E70, Ukraine U1098159 CA E70 INTERNATIONAL-RECERTIFIED U1098163 CA,E70,JAPAN-RECERTIFIED R1098159 CA E70 International - Rental
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 2102753 (Shielded DC Power Cord)
Basic UDI-DI:	N/A
Control Indicator:	**Initial Issue Date** / **REF (Part Number(s))** August 2, 2012 1098159 October 8, 2013 1098163 June 11, 2014 1098161 August 26, 2015 1098162 November 24, 2015 1125426 January 12, 2017 1130729 July 25, 2017 IT1098159 September 15, 2018 1138050 October 10, 2019 FR1098159 September 1, 2020 1140677 March 28, 2021 U1098159, U1098163, R1098159
Global Medical Device Nomenclature code (GMDN) and Description	43947 Mechanical positive pressure airway secretion-clearing device

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 9
Conformity Assessment Route	The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified by Annex II (excluding 4) of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany Identification Number: 0123
Certificate(s) Issued	EC Certification as evidenced by certification number 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.

EU Directive	**Directive 2015/683 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*
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 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 13485:2016 as evidenced by certificate number Q5 015581 0609
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: 14 March 2022

14 MAR 2022

Printed Name: Daria Brown

Place of Issue: Pittsburgh, PA, USA

Title: Senior Manager, Regulatory Affairs

This declaration is valid until: 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 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	
ISO 10993-1:2018	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	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	
IEC 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