EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102423
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:	CoughAssist E70 Accessories
Product Type:	Battery cable, cable adapter
Intended Purpose:	Foot Pedal provides the caregiver can do manual chest thrust while holding the interface. The External Battery Cable provides for safe connection to a standard deep-cycle, lead acid battery to the CoughAssist E70 device. The Auto DC Cable Adaptor provides for a safe connection to a standard automotive electrical system to the CoughAssist E70 device
Product Part Number(s) and Descriptions:	The following Finished Goods are compliant with 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) 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: 1047295 External Battery Cable 1067424 Auto DC Cable Adapter
Product Options/Accessories Part Number(s) and Descriptions:	N/A
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: / Part Number: August 5, 2012 / 1059017 March 13, 2019 / 1067424
Global Medical Device Nomenclature code (GMDN) and Description	Part Number : / GMDN Code: 1059017 47487 Electrical-only medical device connection cable, reusable 1067424 47487 Electrical-only medical device connection cable, reusable

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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 I based on Annex IX and Rule 1 (1059017, 1046972, and 1040420)
Conformity Assessment Route	The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and Annex VII of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request
Notified Body Name, Address, and ID	Not applicable for class I devices.
Certificate(s) Issued	N/A
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)**
Risk Classification	*Category 8, medical device, according to 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. 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: EC Certificate: G1 015581 0608 EN ISO 13485 Certificate: Q5 015581 0607 MDSAP ISO 13485 Certificate: QS6 015581 0610 ISO 13485 and Annex VII of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request

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

Daria Brown

Printed Name:
Daria Brown

Title: Sr. Manager, Regulatory Affairs

Date of Issue: 06 JANUARY 2021

06 JAN 2021

Place of Issue: Monroeville, PA, USA

3. Attachment A
Standards and/or Common Specifications

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 disturbances - 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
Biocompatibility	
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
Other Standards	
Accompany Documents and Labeling	
EN 1041: 2008+A1/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 – Part 1: Application of usability engineering 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