EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2100160
Revision v15

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:	Alice PDx
Product Type:	Polysomnography System
Intended Purpose:	The Alice PDx is a multi-function recording device that collects and stores physiological signals. The recorded data is downloaded, presented graphically on a computer screen, and may be printed for diagnostic review by clinicians/physicians to aid in the diagnosis of respiratory sleep disorders or other physiological disorders. The Alice PDx may be used on adults in the home or hospital/institutional environment
Product Part Number(s) and Descriptions:	1043844 Alice PDx Portable Sleep Diagnostic System INTL CN1043844 Alice PDx Portable Sleep Diagnostic System China 1057624 Alice PDx Unit Only Warranty Exchange INTL R1047990 Alice PDx Portable Sleep Diagnostic System, Japan, Rental R1043844 Alice PDx Portable Sleep Dia Sys, INTL, Rental RBR1043844 Alice PDx Portable Sleep Dia Sys, INTL, Rental 1047990 Alice PDx Portable Sleep Diagnostic System, JP BR1043844 Alice PDx Portable Sleep Diagnostic System, BR 1057626 Alice PDx Unit Only, Warranty Exchange, JP 1058373 Alice PDx Core System without Sensors, JP 1058370 Alice PDx Core System without Sensors, INTL
Product Options/Accessories Part Number(s) and Descriptions:	*This declaration also includes the following product options and accessories:*

Part Number	Description
1040810	Alice PDx ECG Yoke Cable, Intl
1048415	Alice PDx ExG Yoke Cable, Intl
RBR1048415	Cable, ExG Yoke, Alice PDx, Intl. Rental
RBR1040810	Alice PDx ECG Yoke Cable, Intl Rental

Basic UDI-DI:	*N/A*

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Control Indicator:	Initial Issue Date:	Part Number:
	October 16, 2008	1043844, 1040810, 1048415
	January 9, 2009	1057624
	April 30, 2013	CN1043844
	March 15, 2017	RBR1043844, RBR1040810, RBR1048415, R1047990, R1043844
	January 05 2010	1047990, 1057626, 1058373
	July 18, 2020	BR1043844
	September 14,2016	1058370
Global Medical Device Nomenclature code (GMDN) and Description	62230 Home-use sleep apnoea recording system	

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 10
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	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: 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.

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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) 2017/2102 (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. 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: 2 June 2021

Printed Name: Katelyn Manning

Place of Issue: Monroeville, PA

Title: Sr. Manager, Regulatory Affairs

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 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility. Requirements and tests
Particular Safety Standards	
Biocompatibility	
EN 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
EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Pulse Oximetry	
ISO 80601-2-61:2017	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Other Standards	
Accompany Documents and Labeling	
EN 15986:2011	Symbols for use in the labeling of medical devices: Requirements for labelling of medical devices containing phthalates
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2017	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 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Cleaning and Disinfection	
ISO 17664: 2017	Processing of health care products-Information to be provided by the medical device manufacturer for the processing of medical devices-Part 1: Devices that require cleaning followed by disinfection and/or sterilization