EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101100
Revision v23

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 6 Lab Diagnostic Systems
Product Type:	Polysomnography Device
Intended Purpose:	The Alice 6 System is a Polysomnography System (PSG) that is intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper-based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and, is not intended for use as an automated apnea monitor.
Product Part Number(s) and Descriptions:	The following devices use flow gen 1068747: 1063315 Alice 6 Base Station System, LDx INT JP1063315 Alice 6, Base Station System, LDx, JP 1134047 Alice 6, Base Station System, LDx, Intl, with Masimo The following devices use flow gen 1068724: 1063312 Alice 6 Base Station System, LDE INT JP1063312 Alice 6, Base Station System, LDE, JP 1134046 Alice 6, Base Station System, LDE, Intl, with Masimo The following devices use flow gen 1068717: 1063547 Alice 6 LDxN Headbox, Intl BR1063547 Alice 6 LDXN Headbox, BR The following devices use flow gen 1068694: 1063553 Alice 6 LDxS Headbox, Intl BR1063553 Alice 6 LDXS Headbox, BR The following devices use flow gen 1068691: 1063550 Alice 6 LDE Headbox, Intl BR1063550 Alice 6 LDE Headbox, BR The following device uses flow gen 1122300: CN1063312 Alice 6 Base Station System, LDE, China The following device uses flow gen 1122301: CN1063315 Alice 6 Base Station System, LDx, China The following device uses flow gen 1126603: CN1063547 Alice 6 LDxN Headbox, China The following device uses flow gen 1126606:

	CN1063550 Alice 6 LDE Headbox, China The following device uses flow gen 1126604: CN1063553 Alice 6 LDXS Headbox, China The following device uses flow gen 1099355: BR1063312 Alice 6 Base Station System, LDE, BR The following device uses flow gen 1099356: BR1063315 Alice 6 Base Station System, LDx, BR R1063312 Alice 6, Base Station System, LDE, Rental R1063315 Alice 6,Base Station Sys, LDx, INTL, Rental 1063474 RP, Alice 6 Base Station, LDE, INTL 1074646 RP, Alice 6 Base Station, LDx INTL
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 2102194 (oximetry) This declaration also includes the following product options and accessories:

Part Number	Description
1101087	Alice, LoFlo Starter Kit
1101840	Alice 6, Accessory, Sensor Kit, Adult, INT
1101841	Alice 6, Accessory, Sensor Kit, Infant, INT
C1068724	Alice 6 Conversion, LDE Intl
C1068747	Alice 6 Conversion, LDx Intl
1076592	Alice 6 Pressure Sensor, International

Basic UDI-DI:	*N/A.*	
Control Indicator:	Initial Issue Date:	Part Number:
	April 26, 2011	1063315, 1063312, 1063547, 1063553, 1063550
	June 16, 2011	1076592
	June 28, 2011	C1068724, C1068747
	July 20, 2015	CN1063312, CN1063315, CN1063547, CN1063550, CN1063553
	November 05, 2015	JP1063312, JP1063315
	March 23, 2016	BR1063312, BR1063315, BR1063547, BR1063550, BR1063553
	June 17, 2016	1101840, 1101841, 1101087
	February 22, 2017	1068747, 1068724, 1068717, 1068694, 1068691, 1122300, 1122301, 1126603, 1126606, 1126604, 1099355, 1099356
	June 14, 2017	1134046, 1134047
	March 15 2017	R1063312, R1063315
	June 10,2011	1063474 1074646

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Global Medical Device Nomenclature code (GMDN) and Description	33843 Polysomnograph

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. Refer to Attachment A.

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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*

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, USA*

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 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