RESPIRONICS®

DECLARATION OF CONFORMITY

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668
USA
Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name	RUSleeping RTS
Product Type	Sleep Apnea Screening Device
Product Part Number	1048540 RUSleeping RTS, International CN1048540 RUSleeping RTS, China
Control Designator	Part Number / Initial Issue Date: 1048540 December 13, 2007 CN1048540 September 4, 2014
Device Classification, Annex and Rule	Class IIa, Annex IX, Rule 10
Global Medical Device Nomenclature Code (GMDN)	62230 Home-use sleep apnoea recording system
Product Options/ Accessories	Cannula sensor

To which this Declaration relates is in conformity with the provisions of Council Directive:
1. 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC
2. 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE)

The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified by Annex II-Section 3.2 of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.

Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123

Authorized EU Representative	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060

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.

Standards:

The products listed above are fully compliant with the harmonized standards listed below.

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 60601-1-6:2010/ 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 11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-2:2007	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
Other Standards	
Risk Management	
EN ISO 14971:2012	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
Software	
EN 62304:2006/ A1:2015	Medical device software. Software life-cycle processes
Labeling	
EN 1041: 2008	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
Biocompatibility	
EN ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
RoHS	
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Name	Michelle Brinker
Title	Senior Regulatory Affairs Manager
Signature	Michelle Brinker
Date (MM/DD/YYYY)	12/13/2018
Place of Issue	Monroeville