CE 0123

DECLARATION OF CONFORMITY

PHILIPS
RESPIRONICS

Respironics Respiratory Drug Delivery (UK) Ltd
Chichester Business Park
City Fields Way, Tangmere
Chichester, PO20 2FT, UK.

Declares under our sole responsibility that the product:

Product Name: **Sami The Seal (Compressor Nebulizer System)**

Product Part Number: 1093268; 1093235; 1093270.

Start of CE marking: May 4, 2012

Device Classification: IIa Rule: 11

Global Medical Device Nomenclature Code (GMDN): 35457

Product Options/Accessories: Sidestream Handset, Tucker Mask

To which this Declaration relates is in conformity with the provisions of:

- **Council Directive: 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC.**
- **Council Directive 2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment.**

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and 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*
Zertifizierstelle
Ridlerstrasse 65 - 80339, München
Germany
Identification Number: 0123

Note that the Notified Body number does not apply to the RoHS Directive.

Authorized EU Representative: N/A – Manufacture is UK based.

Supplementary Information:
The products listed above have been tested in a typical configuration as described in the manufacturer's accompanying documentation, and are fully compliant with the harmonized standards listed below. 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:

Harmonized Standard:	**Title:**
EN 60601-1:2006/AC:2010	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2: 2007/AC:2010	Medical electrical equipment – Part 1-2: General requirements for safety Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
EN 60601-1-11: 2010	Medical electrical equipment-Part 1-11: General requirements for basic safety and essential Performance.
EN ISO 14971: 2012	Medical devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.
EN 13544-1: 2007 + A1 2009	Respiratory Therapy Equipment – Part1: Nebulizing Systems and their Components.
ISO 13485:2012 AC/2012	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN 1041:2008	Information supplied by the manufacturer of medical devices.

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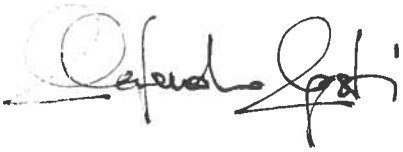
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Signature: 

Date: 06 AUG 15

Printed Name: A AGOSTI

Place of Issue: Chichester, PO20 2FT, UK

Title: QA/RA Manager