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: **InnoSpire Essence and InnoSpire Elegance Compressor Nebulizer Systems**

Product Part Number: 1099973, 1099971, 1099970, 1099967, 1100309, 1099965, 1099964, 1102462, 1102463, 1102461, 1102460, 1102174, 1102173, 1112261

Start of CE marking: 25 JULY 2012

Device Classification: IIa Rule: 11

Global Medical Device Nomenclature Code (GMDN): 35457

Product Options/Accessories: Primary Care Pack, Patient Pack, System 22 Air 02 Supply Tubing, Adult System Aerosol Mask, Child System Aerosol Mask, Sidestream Disposable, Sidestream Durable Nebulizer, Disposable Angled Mouthpiece, Durable Compressor Tubing, Adult Durable Sidestream Kit, Child Durable Sidestream Kit, Durable Sidestream Kit W/Mouthpiece.

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: 2005 + CORR.1 (2006) +CORR.2 (2007) Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2: 2007 Medical electrical equipment – Part 1-2: General requirements for safety Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
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

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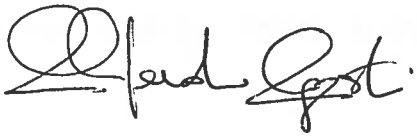
EN 50581: 2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Signature: 

Date: 22 JULY 2014

Printed Name: A AGOSTI

Place of Issue: Chichester, PO20 2FT, UK

Title: QA/RA Manager

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The following is a list of the product options and accessories, including part numbers:

DESCRIPTION	PART NUMBER
Primary Care Pack	2350
Patient Pack	2010A
System 22 Air 02 Supply Tubing	1020 & 1020A
Adult System Aerosol Mask	1100, 1100A & 1100E
Child System Aerosol Mask	1120, 1120A & 1120E
Sidestream Disposable	4445 & 4445A
Sidestream Durable Nebulizer	1201, 1200A & PT1200
Disposable Angled Mouthpiece	1601, 1601A & 1601E
Durable Compressor Tubing	2150A
Adult Durable Sidestream Kit	1223A
Child Durable Sidestream Kit	1224A
Durable Sidestream Kit W/Mouthpiece	1225A