

DECLARATION OF CONFORMITY

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: July 25, 2012

Device Classification Class 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.

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

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:

EN 60601-1: 2005 + CORR.1 (2006) +CORR.2 (2007)

EN 60601-1-2: 2007

EN ISO 14971: 2012

EN ISO 15223-1:2012

EN 13544-1: 2007 + A1 2009

ISO 13485:2012 AC/2812

Title:

Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance

Medical electrical equipment – Part 1-2: General requirements for safety Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Medical devices – Application of Risk Management to Medical Devices

Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.

Respiratory Therapy Equipment – Part1: Nebulizing Systems and Their Components

Medical devices - Quality management systems - Requirements for

Signature:



Date: 08 JAN 2014

Printed Name: ALESSANDRO 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 O2 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