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: **SIDESTREAM DISPOSABLE AND SIDESTREAM REUSABLE NEBULIZER HANDSETS**
SIDESTREAM PLUS NEBULIZER HANDSET

Product Part Number: See attached list

Start of CE marking: September 8th 2009

Device Classification: Class IIa Rule: 11

Global Medical Device Nomenclature Code (GMDN): 35457

Product Options/Accessories: See attached list

Valid until: 05-APR-2022

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 certail hazardous substance 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*

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 ISO 14971: 2012	Medical devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2017	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.
EN 13544-1: 2007 + A1 2009	Respiratory Therapy Equipment – Part1: Nebulizing Systems and Their Components
EN 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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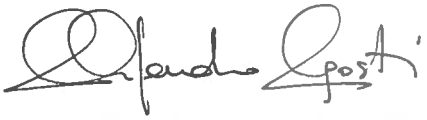
Signature: 

Date: 16 MAY 17

Printed Name: Alessandro Agosti
Title: QA/RA Manager

Place of Issue: Chichester, PO20 2FT, UK

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

DESCRIPTION	PART NUMBER
SIDESTREAM DISPOSABLE	**Part Number**
SIDESTREAM DISPOSABLE. AND ADULT MASK (50 PACK)	1036160
SIDESTREAM DISPOSABLE-50/CS	4445
DISPOSABLE SIDESTREAM	4445A
SIDESTREAM DISPOSABLE-250/CS	4460
PRIMARY CARE PACKS X 40 -40/CS	2350
SIDESTREAM TUBING AND ADULT MASK-50/CS	4446
SIDESTREAM DISPOSABLE AND TUBING ANDCHILD MASK-50/CS	4447
SIDESTREAM DISPOSABLE AND TUBING-50/CS	4448
SS DISPOSABLE NEB, ADULT MASK, TUBING	4446A
SIDESTREAM WITH CHILD MASK AND TUBING	4447A
SIDESTREAM DISPOSABLE, TUBING, ANGLE M/P	4448A
DISPOSABLE SIDESTREAM WITH ANGLED MOUTHPIECE 100 CAS	1072039
SIDESTREAM DURABLE	**Part Number**
DURABLE SIDESTREAM CAS-50/CS	1201
SIDESTREAM DURABLE NEBULIZER (EACH)	1200A
SIDESTREAM DURABLE NEBULIZER-10/CS	PT1200
PATIENT PACK (EA)	2010A
PATIENT PACK (NORWAY) (50/CS)	2010N
80A01 DURABLE SIDESTREAM KIT	1223A
CHILD DURABLE SIDESTREAM KIT	1224A
DURABLE SIDESTREAM KIT AND (EA)	1225A
SIDESTREAM REUSABLE KIT WITH TUCKER MASK	1101484
SIDESTREAM REUSABLE PATIENT PACK WITH FILTERS AND MASKS	1100311
SIDESTREAM PLUS NEBULIZER HANDSET	**Part Number**
SIDESTREAM PLUS (EU) W MOUTHPIECE	1092001