

DECLARATION OF CONFORMITY

Respironics, Inc
1001 Murry Ridge Lane
Murrysville, PA 15668-8550
Tel: 800-345-8443

Declares under our sole responsibility that the product:

Product Name: Circuit Accessories

Product Part Number: 302312 Plateau Exhalation Valve (PEV), Single
312010 O2 Enrichment Attachment, Box of 10
312710 O2 Enrichment Attachment, Single
332113 Whisper Swivel II
532316 Lightweight Tubing, 6 Foot
1006121 Reusable Patient Circuit with PR Line
1007800 High Temperature Tubing, 6 Foot
1032907 Reusable Performance Tubing, 6 Foot

Control Designator: Initial Issue Date: Part Numbers:
March 19, 2003 312010, 312710, 532316
November 14, 2006 302312, 332113, 1006121, 1007800, 1032907

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device Nomenclature Code (GMDN): 44550 Breathing Circuit Tube

Product Options/Accessories: None

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
Ridlerstrasse 65
80339 München, Germany

Notified Body Identification Number: 0123

Authorized EU Representative: Respironics Deutschland
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.

Signature: *Roger E Hyde*

Date: *6-20-2013*

Printed Name: Roger Hyde

Place of Issue: Monroeville

Title: Director, Quality and Regulatory
Patient Interface