CE 0123

DECLARATION OF CONFORMITY

RESPIRONICS®

Respironics New Jersey Inc.
5 Wood Hollow Road
Parsippany, NJ 07054
USA

Declares under our sole responsibility that the product:

Product Name: Evolution, Compressor Nebulizer System

Product Part Number:
1509878 INVACARE STRATOS PRO EUROPE

91488 LINY AL-200

Control Designator: June 17, 2010
Device Classification and Rule: Class IIa, Rule 11
Global Medical Device Nomenclature Code (GMDN): 35457
Product Options/Accessories: Ref to MEDELJETPRO-DHF-007 and JETPRO-DHF-007

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
D-80339 Munich, Germany

Supplementary Information: N/A

Authorized EU Representative: Peter Hebblethwaite, Respironics Deutschland GmbH
Gewerbestrasse 17 - 82211 Herrsching - Germany
Tel: +49 8152 930640

Harmonized Standard:	Title:
EN 60601-1	Medical electrical equipment – Part 1: General requirements safety
EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility – Requirements and tests
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN 980	Symbols for use in the labelling of medical devices
EN 13544-1	Respiratory therapy equipment – Part1: Nebulizing systems and their components
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing

Signature: Lauren Ziegler Date: July 9, 2011

Printed Name: Lauren Ziegler Place of Issue: Parsippany, NJ 07054 USA

Title: Director of QA/RA and Clinical Affairs