



**DECLARATION OF CONFORMITY**  
**LoFlo Sidestream Sampling Accessories**  
**WC DOC #: 1023897MC-A**

**RESPIRONICS®**  
 Respironics Novamatrix, LLC  
 5 Technology Drive  
 Wallingford, CT 06492 USA

**This declaration of conformity is issued under the sole responsibility of the manufacturer.**

Product Name: LoFlo Sidestream Sampling Accessories

Product Model Number or Designator:

Part Number	Description	Effective Date
3468ADH-00	Adult Nasal CO <sub>2</sub> Sampling Cannula w/Dehumidification Tubing	May 26, 2010
3468ADU-00	Adult Nasal CO <sub>2</sub> Sampling Cannula	January 12, 2006
3468INF-00	Infant/Neonatal Nasal CO <sub>2</sub> Sampling Cannula	January 12, 2006
3468INH-00	Infant/Neonatal Nasal CO <sub>2</sub> Sampling Cannula w/Dehumidification Tubing	May 26, 2010
3468PED-00	Pediatric Nasal CO <sub>2</sub> Sampling Cannula	January 12, 2006
3468PEH-00	Pediatric Nasal CO <sub>2</sub> Sampling Cannula w/Dehumidification Tubing	May 26, 2010
3469ADH-00	Adult Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula w/Dehumidification Tubing	May 26, 2010
3469ADU-00	Adult Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula	January 12, 2006
3469INF-00	Infant/Neonatal Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula	July 13, 2007
3469INH-00	Infant/Neonatal Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula w/Dehumidification Tubing	May 26, 2010
3469PED-00	Pediatric Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula	January 12, 2006
3469PEH-00	Pediatric Nasal CO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula w/Dehumidification Tubing	May 26, 2010
3470ADH-00	Adult Nasal /OralCO <sub>2</sub> Sampling Cannula w/Dehumidification Tubing	May 26, 2010
3470ADU-00	Adult Nasal /OralCO <sub>2</sub> Sampling Cannula	January 12, 2006
3470PED-00	Pediatric Nasal /OralCO <sub>2</sub> Sampling Cannula	January 12, 2006
3470PEH-00	Pediatric Nasal /OralCO <sub>2</sub> Sampling Cannula w/Dehumidification Tubing	May 26, 2010
3471ADH-00	Adult Nasal /OralCO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula w/Dehumidification Tubing	May 26, 2010
3471ADU-00	Adult Nasal /OralCO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula	January 12, 2006
3471PED-00	Pediatric Nasal /OralCO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula	January 12, 2006
3471PEH-00	Pediatric Nasal /OralCO <sub>2</sub> Sampling/O <sub>2</sub> Delivery Cannula w/Dehumidification Tubing	May 26, 2010

Control Indicator: Reference the effective date in the table above

Device Classification: Class IIa, Rule 2 according to Annex IX of Council Directive 93/42/EEC

Global Medical Device Nomenclature (GMDN) Code and Title:  
 36306 Carbon Dioxide Sampling Nasal Oxygen Cannula

Product Options/Accessories: None

**The object of the declaration described above is in conformity with:**

- **Council Directive 93/42/EEC concerning medical devices;**
- **ISO 10993-1:2009**

The manufacturer is certified by the Notified Body listed below to ISO 13485:2003 and Annex II, Section 3.2 of the Council Directive 93/42/EEC.

Name/Address of Notified Body: BSI Group  
Kitemark Court  
Davy Avenue, Knowlhill  
Milton Keynes, MK5 8PP  
United Kingdom

EC Certificate Number: No. CE 01723

Authorized EU Representative: Respirationics Deutschland  
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Germany  
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Signed for and on behalf of Respirationics Novamatrix, LLC  
Dennis Daniels  
Director, Quality and Regulatory  
Wallingford, CT

March 11, 2015

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Date