CE 0086

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

RESPIRONICS
Respironics Novametrix, 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 | GMDN |
|---|---|---|---|
| 3469ADH-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula with Dehumidification Tubing ADULT NASAL | May 26, 2010 | 36306 Carbon Dioxide Sampling Nasal Oxygen Cannula |
| 3469ADU-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula ADULT NASAL | January 12, 2006 | |
| 3469INF-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula INFANT/NEONATAL NASAL | July 13, 2007 | |
| 3469INH-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula with Dehumidification Tubing INFANT/NEONATAL NASAL | May 26, 2010 | |
| 3469PED-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula PEDIATRIC NASAL | January 12, 2006 | |
| 3469PEH-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula with Dehumidification Tubing PEDIATRIC NASAL | May 26, 2010 | |
| 3471ADH-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula with Dehumidification Tubing ADULT ORAL/NASAL | May 26, 2010 | |
| 3471ADU-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula ADULT ORAL/NASAL | January 12, 2006 | |
| 3471PED-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula PEDIATRIC ORAL/NASAL | January 12, 2006 | |
| 3471PEH-00 | LoFlo $CO_2$ Sampling $O_2$ Delivery Cannula with Dehumidification Tubing PEDIATRIC ORAL/NASAL | May 26, 2010 | |
| 3472ADU-00 | LoFlo Airway Adapter Kit ADULT/PEDIATRIC | January 12, 2006 | 45566 Gas sampling/monitoring respiratory tubing, single use, non-sterile |
| 3472INF-00 | LoFlo Airway Adapter Kit INFANT/NEONATAL | January 12, 2006 | |
| 3473ADU-00 | LoFlo Airway Adapter Kit w/ Dehumidification Tubing Adult/Pediatric | January 12, 2006 | 42049 Gas Analyzer Tubing Set, Dehumidification, Single Use |
| 3473INF-00 | LoFlo Airway Adapter Kit w/Dehumidification Tubing INFANT/NEONATAL | January 12, 2006 | |

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: Refer to table above

Product Options/Accessories: None

The object of this Declaration described above is in conformity with: Council Directive 93/42/EEC (Medical Device Directive)

Conformity Assessment Route: Annex II, EC Declaration of Conformity.

The manufacturer is certified by the Notified Body listed below to ISO 13485:2016 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
Expiry 18JUL2022

Authorized EU Representative:

Respironics Deutschland GmbH & Co. KG
Gewerbestrasse 17
82211 Herrsching
Germany

Signed for and on behalf of Respironics Novametrix, LLC
Sunny Yi
Manager, Regulatory Affairs

Dec 3, 2012
Date

QAF90280verB
Signature/Date: EDMS