



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	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	45566 Gas sampling/monitoring respiratory tubing, single use, non-sterile
3472ADU-00	LoFlo Airway Adapter Kit ADULT/PEDIATRIC	January 12, 2006	
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	
3473INF-00	LoFlo Airway Adapter Kit w/Dehumidification Tubing INFANT/NEONATAL	January 12, 2006	42049 Gas Analyzer Tubing Set, Dehumidification, Single Use

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)

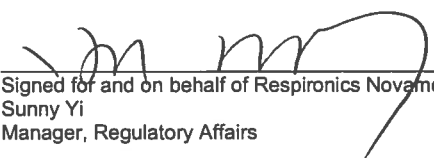
Conformity Assessment Route: Annex II, EC Declaration of Conformity.

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, Knowhill
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 Novamatrix, LLC
Sunny Yi
Manager, Regulatory Affairs

Dec 3, 2012
Date