CE 0086

DECLARATION OF CONFORMITY
LoFlo Sidestream CO_2 Module
WC DOC #: 1022054MC3

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: Respironics LoFlo Sidestream CO_2 Module

Product Model Number or Designator:

Part Number	Description	Effective Date
1022054	Respironics LoFlo Sidestream CO_2 Module	January 12, 2006
1050797	Respironics LoFlo Sidestream CO_2 Module for Goldway	November 24, 2006
1097955	Respironics Alice, LoFlo, C5 Sidestream Module	May 16, 2010
1069879	Respironics LoFlo Sidestream CO_2 Module for GE	February 26, 2018

Control Indicator: Reference the effective date in the table above

Device Classification: Class IIb, Rule 10 according to Annex IX of Council Directive 93/42/EEC

Global Medical Device Nomenclature (GMDN) Code and Title:
36554 Patient Monitoring System Module, Carbon Dioxide

Product Options/Accessories: Please refer to 1022054TF for a list of applicable accessories

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

- Council Directive 93/42/EEC concerning medical devices

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

Dec 3, 2018
Date