EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737191 R000

Manufacturer: Respironics Novametrix, LLC

Address:
3000 Minuteman Road
Andover
MA
01810
USA

Single Registration Number: US-MF-000007951

EU Authorised Representative: Philips Medical Systems Nederlands B.V.

Address:
Veenpluis 6
Best
5684PC
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-03-04**

Current Issue Date: **2023-09-26**

Starting Validity Date: **2023-09-26**

Expiry Date: **2027-03-03**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Capnostat 5 and LoFlo Modules and Sensors	Intended to provide carbon dioxide monitoring to a host monitoring system during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care. CapnoTrak Patient Interface

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
CO2/Flow Sensors	Class IIa
Airway Adapters	Class IIa
Patient Interface Accessories	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-03-04	3297256	Issued
Current	30007795	Amended – Change of manufacturer address to: 3000 Minuteman Road Andover MA 01810 USA.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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