ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 015581 0611 Rev. 00

Manufacturer:

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville PA 15668
USA

Product Category(ies):

Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Electroencephalograph, Sleep Therapy Diagnostic Devices, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Nasal Cannulae, and Sleep Position Training Devices for the Treatment of Positional Sleep Apnea. Non-active medical devices for respiratory care (Respiratory muscle trainers, nebulizers, mouthpieces, facemasks, tubing, connectors and T pieces) and active medical devices for respiratory care (nebulizers and ventilators)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 015581 0611 Rev. 00

Report No.: 72161399

Valid from: 2021-03-15
Valid until: 2024-05-26

Date, 2021-03-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Identification of the device(s)	DreamStation 2 CPAP/Auto CPAP DreamStation 2 Advanced CPAP/Auto CPAP
Product MDD Declaration of Conformity	2103229
Product ERTFI	2103149

Manufacturer name	Respironics, Inc.
Manufacturer address and contact details	1001 Murry Ridge Lane Murrysville PA 15668 USA
Single Registration Number (SRN) (if available)	US-MF-000002301

Authorised Representative name (if applicable)	Philips Medical Systems Nederland B.V
Authorised Representative address and contact details	Veenpluis 6 5684PC Best The Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000001422

Notified body Name and Number	TUV SUD, CE 0123
Directive Certificate number(s) to which this confirmation is made	MDD EC Cert No. G1 015581 0611
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26 MAY 2024
End date of extended validity/transition period	31 DEC 2028
Notified Body name and number where the MDR application was lodged/contract signed	TUV SUD, CE0123 – 15 July 2022
Substitute Devices(s)	None

EU MANUFACTURER'S DECLARATION

RESPIRONICS®

Doc Number: ER 2249915
Revision: 00

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, **Appendix A**, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule (see **Appendix A**) and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

❖ **Directive Certificate(s)** as listed above or in the attached schedule (**Appendix A**)

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒**Expired/expires *after* 20 March 2023**:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

❖ **Upclassified devices**

- In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☒ Not applicable.

❖ **Quality Management System (QMS)**

- Choose *one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

❖ **Device(s) as listed in the attached schedule (Appendix A)**

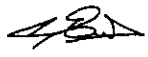
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

EU MANUFACTURER'S DECLARATION

RESPIRONICS®

Doc Number: ER 2249915
Revision: 00

Signed for and on behalf of the manufacturer:

Person Responsible for Regulatory Compliance (PRfRC) Regulatory and Quality		
Title	**Name**	**Signature and Date**
Head of Regulatory Affairs	Lee Evans Lee.Evans@philips.com Phone: +1 (732) 5072639	 May 17, 2024 *Electronically signed by: Lee Evans* *Reason: "I Approve"* *Date: May 17, 2024 19:27 EDT*
Head of Quality for Sleep and Respiratory Care	Thomas Fallon Email: tom.fallon@philips.com Phone +1 (978) 9415572	Thomas J Fallon May 22, 2024 *Electronically signed by: Thomas J Fallon* *Reason: "I Approve"* *Date: May 22, 2024 08:35 CDT*

Appendix A: Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Table 1. Identification of the devices

Identification of the device(s) *Product Category* • Device Name	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number**	**End date of extended validity / transition period**
Positive Airway Pressure Units (Bi-level Continuous)/Non-Continuous Ventilators • DreamStation 2 CPAP/Auto CPAP • DreamStation 2 Advanced CPAP/Auto CPAP	G1 015581 0611 Rev.00	2024-05-26	TUV SUD, CE 0123	2028-12-31

Table 2. Part Numbers within scope of EU Manufacturer's Declaration

Identification of the device(s) *Product Category* • Device Name	**Applicable Part Numbers** *Part Number*	*Part Number Description*
Positive Airway Pressure Units (Bi-level Continuous)/Non-Continuous Ventilators • DreamStation 2 CPAP/Auto CPAP • DreamStation 2 Advanced CPAP/Auto CPAP	BLX410H15C	DS2 CPAP w/Humid cell/BT, BL
	BLX420H15C	DS2 Adv CPAP w/Humid cell/BT, BL
	BLX510H15C	DS2 Auto CPAP w/Humid cell/BT, BL
	BLX520H15C	DS2 Adv Auto CPAP w/Humid cell/BT, BL
	DEX420H13C	DS2 Auto CPAP w/Humid cell/BT, DE
	DEX520H13	DS2Adv Auto CPAP w/Humid BT only, DE
	DEX520H13C	DS2Adv Auto CPAP w/Humid cell/BT, DE
	EEX410H15C	DS2 CPAP w/Humid cell/BT, EE
	EEX420H15C	DS2Adv CPAP w/Humid cell/BT, EE
	EEX510H15C	DS2 Auto CPAP w/Humid cell/BT, EE
	EEX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, EE
	ESX410H15	DS2 CPAP w/Humid BT only, ES
	ESX410H15C	DS2 CPAP w/Humid cell/BT, ES

Identification of the device(s) *Product Category* • Device Name	**Applicable Part Numbers** *Part Number* *Part Number Description*
	ESX420H15C DS2Adv CPAP w/Humid cell/BT, ES ESX520H15C DS2Adv Auto CPAP w/Humid cell/BT, ES EUX410H15 DS2 CPAP w/Humid BT only, EU EUX410H15C DS2 CPAP w/Humid cell/BT, EU EUX420H15 DS2Adv CPAP w/Humid BT only, EU EUX420H15C DS2Adv CPAP w/Humid cell/BT, EU EUX510H15 DS2 Auto CPAP w/Humid BT only, EU EUX510H15C DS2 Auto CPAP w/Humid cell/BT, EU EUX520H15 DS2Adv Auto CPAP w/Humid BT only, EU EUX520H15C DS2Adv Auto CPAP w/Humid cell/BT, EU FRX521H14C DreamStation 2 Auto CPAP Advanced Humid/P Flex/Cell/BT, FR GBX420H15C DS2Adv CPAP w/Humid cell/BT, GB GBX520H15C DS2Adv Auto CPAP w/Humid cell/BT, GB ITX410H15 DS2 CPAP w/Humid BT only, IT ITX410H15C DS2 CPAP w/Humid cell/BT, IT ITX420H15C DS2Adv CPAP w/Humid cell/BT, IT ITX510H15 DS2 Auto CPAP w/Humid BT only, IT ITX510H15C DS2 Auto CPAP w/Humid cell/BT, IT ITX520H15C DS2Adv Auto CPAP w/Humid cell/BT, IT NDX510H15C DS2 Auto CPAP w/Humid cell/BT, ND NDX520H15C DS2Adv Auto CPAP w/Humid cell/BT, ND NDX520T15C DS2Adv Auto CPAP w/Humid/HT cell/BT, ND