PHILIPS

June 2024

To
Mobiak S.A.
Kathiana Akrotiriou
Chania Crete P.C 73100
Greece

Dear customer

We hereby confirm that the Everflo PN 1020006 supplied to date, and which will be purchased have been manufactured according to the certification of the Medical Device Directive 93/42/EEC and have been placed on the EU market before 26 May 2024.

Best Regards

Philips Sleep&Respiratory Care

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2024.06.26 12:48:52
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C=IT
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RSA/2048 bits

PHILIPS

Subject: Product Availability Date: June 13, 2024

Dear Customer,

Philips Medical Systems Nederland B.V. has inventory available for several products. These products were manufactured under the Medical Device Directive 93/42/EEC certification and will have been placed onto the EU market before 26 May 2024.

If you have any questions or need additional information, please reach out to your Philips representative. We appreciate you and thank you for your continued partnership.

Product Family Name	Description	Availability
Philips DreamWisp	Top of head, over the nose minimal contact nasal mask	Until stock depletes
Philips Nuance Pro	Front of face, gel pillows mask	Until stock depletes
Philips Amara Gel	Front of face, gel full face mask with forehead arm	Until stock depletes
Philips Comfort Gel Blue Nasal	Front of face, gel nasal mask with forehead arm	Not available
I-neb AAD Nebulizer	Nebulizer	Not available
SideStream Disposable, Plus, and Reusable Compressor Nebulizers	Nebulizer	Until stock depletes
BiPAP A Series (Silver Series, Legacy); BiPAP A30 EFL; BiPAP A40 EFL	BiPAP ventilators	Not available
NightBalance	Sleep Position Therapy	Not available
Alice NightOne	Diagnostic Device	Not available
Alice PDx	Portable Sleep Diagnostic System	Not available
Alice 6	Diagnostic Sleep System	Not available
Omnilab Advanced +	Titration System	Not available
DreamStation Go	CPAP	Not available
SimplyGo	Portable Oxygen Concentrator	Not available
SimplyGo Mini	Portable Oxygen Concentrator	Until stock depletes
EverFlo	Stationary Oxygen Concentrator	Until stock depletes
Philips AF541	NIV oro-nasal mask, single patient use, hospital	Until stock depletes

Electronically signed by: Michał Grzybowski
Reason: I have reviewed and approve this document
Date: Jun 14, 2024 12:38 GMT+2

Michal Grzybowski
Sleep & Respiratory Care Market Leader EMEA,
Philips

Product Availability Customer letters _MG_1406

Final Audit Report 2024-06-14

Created:	2024-06-14
By:	Anna Florek-Kozakiewicz (anna.florek@philips.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAANnBw7tqkTDQkqeOv81GceAJEa42vxdhr

"Product Availability Customer letters _MG_1406" History

Document created by Anna Florek-Kozakiewicz (anna.florek@philips.com)
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Document emailed to michal.grzybowski@philips.com for signature
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Signer michal.grzybowski@philips.com entered name at signing as Michał Grzybowski
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Signing reason: I have reviewed and approve this document
Signature Date: 2024-06-14 - 10:38:10 AM GMT - Time Source: server- IP address: 155.190.39.5

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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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Product Service

EC Certificate

Full Quality Assurance System
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No. G1 015581 0611 Rev. 00

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