3-5

KARE MEDICAL

Key Points

- Ultra low volume decreases shipping costs (288 pcs in a 20' container)
- Very small visual appearance and non medical look
- Low power consumption&less heat production
- 3 liter version is available for low flow patients, saves from unnecessary power cost and extra weight of 5 liter machines
- No maintenance required for 2 years
- Silent operation

Mini 5 Technical Specifications

Part Number	OXY6500
Operating Voltage	220-240V / AC
Mains Frequency	50-60 Hz.
Power	330 W
Oxygen Flow	0,5-5 LPM
Oxygen Saturation	1-5 L 93 ± 3%
O_2 Monitor	- High Oxygen $\%O_2 > 82\%$ - Low Oxygen $\%O_2 < 82\%$ - Technical Service Required < 70%
Operating Pressure	0,07-0,09 Mpa
Operating Temp.	5-40° C
Gross Weight	17,5 Kgs
Net Weight	15,1 Kgs.
Type	B
Class	II

CE 1984
EN ISO 9001:2008
EN ISO 13485:2003

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-481

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

KARE MEDİKAL ve ANALİTİK CİHAZLAR SANAYİ ve TİCARET LİMİTED ŞİRKETİ (KARE MEDICAL AND ANALYTICAL DEVICES LIMITED COMPANY)

Head Office: Ziya Gökalp Cad. 36/23 Yenişehir Çankaya, Ankara, Turkey
Factory: Ankara II. Organize Sanayi Bölgesi Alcı OSB Mahallesi 2017.Cadde No:24 Sincan, Ankara, Turkey

Products: PAP Therapy Systems, Portable Suction Units, Compressor Nebulizers, Nebulizer Sets, Oxygen Concentrators, Oxygen Humidifiers, Ventilators, Ultrasonic Nebulizers

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.4611.06
Date of first issue:	12 January 2018
Date of last issue:	14 December 2020
Revision Number:	02
Expiry Date:	27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

14 December 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-481, Revision Number: 02

Concerned medical devices;

Product: PAP Therapy Systems
Model: Sleepone Cpap, Sleepone Auto Cpap, Sleepone Pediatric Cpap, Sleepone Bilevel S, Sleepone Bilevel ST, Sleepone Bilevel Auto, Sleepone Bilevel ST Auto, Sleepone Pro SV, Sleepone Pro VT, Sleepone Pro PSV, Sleepone Heated Humidifier, Sleepone Pro PSV Heated Humidifier

Product: Portable Suction Units
Model: Ecoaspir, Ecoaspir Plus

Product: Compressor Neblizers
Model: Hikoneb Aerocare II, Hikoneb A103

Product: Nebulizer Sets
Model: Purebreath Nebulizer Set

Product: Oxygen Concentrators
Model: Hikoneb Oxybreath 10L, Hikoneb Oxybreath Mini 5, Hikoneb Oxybreath Mini 3

Product: Oxygen Humidifiers
Model: Purebreath Nemlendirici 6-3

Product: Ventilators
Model: KMV5010, Sleepone Pro PSV plus

Product: Ultrasonic Nebulizers
Model: Hikoneb 906 S/Lcd, Hikoneb 908 DC

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

14 December 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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CERTIFICATE

KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.

HEAD OFFICE: ZİYA GÖKALP CADDESİ 36/23 YENİŞEHİR
ÇANKAYA - ANKARA - TURKEY
FACTORY: ANKARA II. ORGANİZE SANAYİ BÖLGESİ ALICI OSB MAHALLESİ
2017. CADDE NO: 24 SİNCAN - ANKARA - TURKEY

with a scope of

DESIGN, MANUFACTURE AND SALES OF AEROTHERAPY DEVICES

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "

" None "

ISO 9001:2015

Certificate No	: M 10302
Initial Certification Date	: 04 January 2016
Certification Date	: 14 September 2018
Expiration Date	: 13 September 2021

General Manager

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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.

Quality Management System
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-E4DC-CF69

Last Modified: 14 September 2018 - R 03

CERTIFICATE

KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.

HEAD OFFICE: ZİYA GÖKALP CADDESİ 36/23 YENİŞEHİR
ÇANKAYA - ANKARA - TURKEY
FACTORY: ANKARA II. ORGANİZE SANAYİ BÖLGESİ ALICI OSB MAHALLESİ
2017. CADDE NO: 24 SİNCAN - ANKARA - TURKEY

with a scope of

DESIGN, MANUFACTURING AND DISTRIBUTION OF AEROTHERAPY DEVICES

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 10303
Initial Certification Date	: 04 January 2016
Certification Date	: 14 September 2018
Expiration Date	: 13 September 2021

General Manager

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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 14 September 2018 - R 04

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-7267-741E