



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

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 Nebulizers

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