

## 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 Yenışehir Çankaya, Ankara, Turkey


**Factory:** Ankara İl. Organize Sanayi Bölgesi Alcı OSB Mahallesi 2017.Cadde  
No:24 Sincan, Ankara, Turkey

**Products:** Ultrasonic nebulizers, Piston Type Nebulizers, Piston Type Pediatric Nebulizers, Oxygen Concentrators, Suction Units, CPAP Systems, Oxygen Concentrator Bubble Humidifier, Ventilators

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.4611.03

**Expiry Date:** 11 January 2021



12 January 2018, Istanbul, Turkey

Head of Notified Body

**Enclosure of the EC Certificate:**

**Full Quality Assurance System according to  
Medical Devices Directive 93/42/EEC Annex-II Section 3  
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Concerned medical devices;

**Product:** Ultrasonic Nebulizer  
**Models:** Hikoneb 908 DC, Hikoneb 906 S/LCD

**Product:** Piston Type Nebulizer  
**Models:** Hikoneb Aerocare II, A103

**Product:** Piston Type Pediatric Nebulizer  
**Models:** Aerocare 101, Aerocare 102

**Product:** Oxygen Concentrator  
**Models:** Hikoneb Oxybreath 10L, Hikoneb Oxybreath Mini 3, Hikoneb Oxybreath Mini 5

**Product:** Suction Unit  
**Models:** Ecoaspir, Ecoaspir Plus

**Product:** CPAP Systems  
**Models:** SleepOne CPAP Device, SleepOne CPAP Device with Humidifier, SleepOne Auto CPAP Device, SleepOne Auto CPAP Device with Humidifier, SleepOne Bilevel S Device, SleepOne Bilevel ST Device, SleepOne Bilevel Auto Device, SleepOne Bilevel ST Auto Device, SleepOne Pro SV Device, SleepOne Pro VT Device, SleepOne Pro PSV Device, SleepOne Pediatric CPAP Device

**Product:** Oxygen Concentrator Bubble Humidifier  
**Models:** PureBreath

**Product:** Ventilator  
**Models:** KMV5010, SleepOne Pro PSV Plus Device

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke at the end.

12 January 2018, Istanbul, Turkey

Head of Notified Body