



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: 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

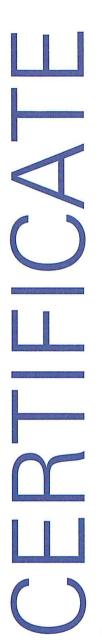
Expiry Date:

11 January 2021

12 January 2018, Istanbul, Turkey

Head of Notified Body







Enclosure of the EC Certificate:

Page 1/1

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

Certificate Number: 1984-MDD-18-481

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

12 January 2018, Istanbul, Turkey

Head of Notified Body