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: 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

Kiwa Certification Services Inc.
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.tr

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

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

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