Certificate

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EC Certificate

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

Certificate Number: 1984-MDD-10-059

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 Medikal ve Analitik Cihazlar Sanayi ve Ticaret Limited Şirketi

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

Products: Ultrasonic nebulizers, piston type nebulizers, oxygen concentrators, suction units, CPAP systems, oxygen concentrator bubble humidifier, ventilator.

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 Meyer for details.

Report Number:	M.4611.01
Date of first issue:	06 November 2010
Revision Number:	12
Date of last issue:	21 September 2016
Expiry Date:	14 December 2017

21 September 2016, Istanbul, Turkey

Head of Notified Body

Kiwa Meyer Certification Services Inc.
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Certificates without seal are invalid.

Digitally signed by Turcanu Ștefan
Date: 2021.06.30 12:50:32 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate

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Partner for progress

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-10-059, Revision Number: 12

Concerned medical devices;

Product: Ultrasonic Nebulizer, **Class:**IIa
Models: Hikoneb®908 DC, Hikoneb®906 HC, Hikoneb®906S/LCD, Hikoneb®Hometype

Product: Piston Type Nebulizer, **Class:**IIa
Models: Hikoneb®Aerocare, Hikoneb®Aerocare II

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

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

Product: Suction Unit, **Class:**IIa, **Model:** Ecoaspir, Ecoaspir Plus

Product: CPAP Systems, **Class:**IIa,
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, **Class:**IIa, **Models: -**

Product: Ventilator, **Class:**IIb, **Model:** KMV5010, SleepOne Pro PSV Plus Device

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

21 September 2016 Istanbul, Turkey

Head of Notified Body

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