



CERTIFICATE



EC Certificate

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

Certificate Number: 1984-MDD-19-563

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:

HÜNKAR ECZA VE MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Akçeşme Mahallesi 2019 Sokak No:5 Merkezefendi, Denizli, Turkey

Products: Nebulizer, Portable Mesh Nebulizer, Infrared Thermometer, Oxygen Masks, Nebulizer Sets

The products defined at the enclosure which is the part of this certificate and contains 1 (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.3979.07
Expiry Date: 17 January 2024

18 January 2019, 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
Certificate Number: 1984-MDD-19-563**

Concerned medical devices;

Product: Nebulizer

Model Number: HNK-NBL-MN, HNK-NBL-S, HNK-NBL-MON, HNK-NBL-S1, HNK-NBL-COM, HNK-NBL-SKY, HNK-NBL-CAR, HNK-NBL-EXT, HNK-NBL-FISH, HNK-NBL-TRV

Product: Portable Mesh Nebulizer

Model Number: HNK-MESH-01

Product: Infrared Thermometer

Model Number: HNK-IR-01, HNK-TB-01

Product: Oxygen Masks

Model Number: 099 101, 099 102, 099 103, 099 104

Product: Nebulizer Sets

Model Number: 099 111, 099 121, 099 131, 099 141, 099 151, 099 161, 099 171, HNK-MESH-01-01, HNK-MESH-01-02, HNK-MESH-01-03

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, appearing to be "U. K. K. K.", written over a horizontal line.

Head of Notified Body

18 January 2019, Istanbul, Turkey