

EC Certificate
Production Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-621

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

ELMASLAR İMALAT TIBBİ CİHAZLAR İNŞAAT TAŞIMACILIK
İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM ŞİRKETİ

1.ORGANİZE SANAYİ BÖLGESİ BABÜRŞAH CADDESİ NO:17 SİNCAN-ANKARA -TURKEY

Products: Ultrasonic Nebulizers, Compressor Nebulizer, Oxygen Concentrators, Surgical Aspirators, Sleep Apnea Therapy Devices, Nasal and Full Face Mask, Heated Humidifier

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.2794.12

Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel
Head of Notified Body

28 October 2019, Istanbul, Turkey