



CERTIFICATE



elmaslar

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

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

with a scope of

**DESIGN, MANUFACTURE, DISTRIBUTION, INSTALLATION AND
SERVICES OF ULTRASONIC NEBULIZERS, COMPRESSOR
NEBULIZERS, OXYGEN CONCENTRATORS, SURGICAL ASPIRATORS,
SLEEP APNEA THERAPY DEVICES AND ACCESSORIES**

Has established a quality management system in accordance
with international standard.

“Following elements of the standard are excluded “

“None “

ISO 9001:2015

Certificate No : M 11332
Initial Certification Date : 28 October 2019
Certification Date : 28 October 2019
Expiration Date : 27 October 2022



TÜRKAK BDS NO
YS-5449-9CF8

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.

Last Modified: 28 October 2019 - R 00



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TAŞIMACILIK İTHALAT İHRACAT SANAYİ VE
TİCARET ANONİM ŞİRKETİ**

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Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

"6.4.2" "7.5.2" "7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

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Medical Device Q.M.S.
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO
YS-413E-E103