



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



Quality Management System
TS EN ISO/IEC 17021-1
AB-0006-YS



TÜRKAK BDS NO
YS-5449-9CF8

General Manager

Kiwa Certification Services Inc.

İTOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Turkey

Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74

Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

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



elmastlar

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

1. ORGANİZE SANAYİ BÖLGESİ BABÜRŞAH CADDESİ NO: 17
SINCAN – 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**

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

Certificate No : M 11333
Initial Certification Date : 28 October 2019
Certification Date : 28 October 2019
Expiration Date : 27 October 2022

General Manager

Kiwa Certification Services Inc.

İTOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Turkey

Tel: +90 216 593 25 75 Faks : +90 216 593 25 74

Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

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

CERTIFICATE



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

AB-0006-YS



TÜRKAK BDS NO
YS-413E-E103