



# 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.  
ITOSB 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](http://www.kiwa.com.tr) E-mail: [info@kiwa.com.tr](mailto: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



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**

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](http://www.kiwa.com.tr) E-mail: [info@kiwa.com.tr](mailto: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