



TİBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE



TÜRK STANDARDLARI ENSTİTÜSÜ
bu belge ile

EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI
SAN. TİC. A.Ş. AVRUPA SERBEST BÖLGESİ ŞUBESİ
KARAMEHMET MAH. AVRUPA SERBEST BÖLGESİ
ADNAN ARISOY BULVARI NO:13/305 ERGENE -
TEKİRDAĞ / TÜRKİYE

kuruluşunun TS EN ISO 13485:2012 şartlarına uygun bir TIBBİ
CİHAZLAR KALİTE YÖNETİM SİSTEMİ'ne sahip olduğunu
onaylar.

Belge kapsamı Ek'te verilmiştir



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

SİSTEM BELGELENDİRME GRUP BAŞKANI
HEAD of SYSTEM CERTIFICATION GROUP


GÖKÇEN BİRCAN DEĞERLİYURT

Bu belge belgelendirme şartlarına
uygunluk sağlandığı sürece geçerlidir.

Türk Standardları Enstitüsü Türk Akreditasyon Kurumu TÜRKAK tarafından akredite edilmiştir.
Turkish Standards Institution, has been accredited by the Turkish Accreditation Agency TÜRKAK.

TURKISH STANDARDS INSTITUTION
hereby certifies that the organization

EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI
SAN. TİC. A.Ş. AVRUPA SERBEST BÖLGESİ ŞUBESİ
KARAMEHMET MAH. AVRUPA SERBEST BÖLGESİ
ADNAN ARISOY BULVARI NO:13/305 ERGENE -
TEKİRDAĞ / TÜRKİYE

has a MEDICAL DEVICES QUALITY MANAGEMENT
SYSTEM which fulfills the requirements of the TS EN ISO
13485:2012

Scope of the certificate is given in annex

Belge No / Certificate No

TY-003/05/12

Belge Tarihi / Date of Certificate

29.11.2016

Geçerlilik Tarihi / Valid Until

29.11.2019

Revizyon Tarihi / Date of Revision

29.11.2016

İlk Belge Tarihi / Initial Certification Date

22.02.2005

This certificate is valid provided that compliance
with the certification requirement is maintained.



TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

EK / APPENDIX



Belge No / Certificate No: **TY-003/05/12**

Belge Tarihi / Date of Certificate: **29.11.2016**

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI
SAN. TİC. A.Ş. AVRUPA SERBEST BÖLGESİ ŞUBESİ
KARAMEHMET MAH. AVRUPA SERBEST BÖLGESİ
ADNAN ARISOY BULVARI NO:13/305 ERGENE -
TEKİRDAĞ / TÜRKİYE

Belge Kapsamı:

Scope of the Certificate:

TS EN ISO 13485:2012

TS EN ISO 13485:2012

- ANALOG, DİJİTAL KULAK İÇİ VE KULAK ARKASI
İŞİTME CİHAZLARI
- İŞİTME CİHAZLARI UYARLAMA YAZILIMI(29.11.2016
TARİHİNDEN İTİBAREN)

DESIGN AND PRODUCTION OF

TASARIMI VE ÜRETİMİ

- ANALOG, DIGITAL INTERNAL AND EXTERNAL
HEARING AIDS DEVICES
- FITTING SOFTWARE OF HEARING AIDS(SINCE
29.11.2016)





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

TSE as an IONet Partner hereby states that the organization

**EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI SAN. TİC. A.Ş.
AVRUPA SERBEST BÖLGESİ ŞUBESİ**

KARAMEHMET MAH. AVRUPA SERBEST BÖLGESİ ADNAN ARISOY BULVARI NO:13/305
ERGENE -
TEKİRDAĞ / TÜRKİYE
has implemented and maintains a

which fulfills the requirements of the following standard

TS EN ISO 13485:2012

Issued on: 29-11-2016

for the validity date, please refer to the original certificate * issued by TSE

Registration Number : TR-TY-003/05/12



Michael Drechsel
President of IONet
Gökçen Bircan Degerliyurt
Head of System Certification Group

IONet Partners**:

AENOR Spain AFNOR Certification France AIB-Vingotte International Belgium APCER Portugal
CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KPO Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCB Poland
Quality Austria RR Russia SIGE Mexico SII Israel SIQ Slovenia SIRIM QAS International Malaysia
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IONet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IONet Partner's original certificate and shall not be used as a stand-alone document

** The list of IONet partners is valid at the time of issue of this certificate. Updated information is available under www.ionet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNET Certificate Number :TR-TY-003/05/12

Name and Address of the certified organization

**EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI SAN. TİC. A.Ş.
AVRUPA SERBEST BÖLGESİ ŞUBESİ**

KARAMEHMET MAH. AVRUPA SERBEST BÖLGESİ ADNAN ARISOY BULVARI NO:13/305
ERGENE - TEKİRDAĞ / TÜRKİYE

Scope of the Certificate

DESIGN AND PRODUCTION OF

- ANALOG, DIGITAL INTERNAL AND EXTERNAL HEARING AIDS DEVICES
- FITTING SOFTWARE OF HEARING AIDS(SINCE 29.11.2016)

This annex is only valid in connection with the above-mentioned certificate

13



TURKISH STANDARDS INSTITUTION

