



TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE



TÜRK STANDARDLARI ENSTİTÜSÜ
bu belge ile

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE
TİC. LTD. ŞTİ.
İKİTELLİ OSB DEMİRCİLER SAN. SİT. B7 BLOK
NO:157 34490 BAŞAKŞEHİR -
İSTANBUL / TÜRKİYE

kuruluşunun TS EN ISO 13485:2016 şartlarına uygun bir TIBBİ
CİHAZLAR KALİTE YÖNETİM SİSTEMİ'ne sahip olduğunu
onaylar.

Belge kapsamı Ek'te verilmiştir



Bu belge belgelendirme şartlarına
uygunluk sağlandığı sürece geçerlidir.



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

SİSTEM BELGELENDİRME GRUP BAŞKANI
HEAD of SYSTEM CERTIFICATION GROUP

MESUT DURU

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

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE
TİC. LTD. ŞTİ.
İKİTELLİ OSB DEMİRCİLER SAN. SİT. B7 BLOK
NO:157 34490 BAŞAKŞEHİR -
İSTANBUL / TÜRKİYE

has a MEDICAL DEVICES QUALITY MANAGEMENT
SYSTEM which fulfills the requirements of the TS EN ISO
13485:2016

Scope of the certificate is given in annex

Belge No / Certificate No

TY-022/17-R16

Belge Tarihi / Date of Certificate

27.08.2020

Geçerlilik Tarihi / Valid Until

10.08.2023

Revizyon Tarihi / Date of Revision

27.08.2020

İlk Belge Tarihi / Initial Certification Date

10.08.2017

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-022/17-R16**

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

Belge Tarihi / Date of Certificate: **27.08.2020**

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE
TİC. LTD. ŞTİ.
İKİTELLİ OSB DEMİRCİLER SAN. SİT. B7 BLOK
NO:157 34490 BAŞAKŞEHİR -
İSTANBUL / TÜRKİYE

Belge Kapsamı:

TS EN ISO 13485:2016

- CERRAHİ BEYİN PEDİ, PEDLER
- SABİTLEYİCİ, DESTEKLEYİCİ VE KORUYUCU BANTLAR
- AMELİYAT LAMBASI EL TUTAMAĞI KILIFI

TASARIMI, ÜRETİMİ VE DAĞITIMI

TSE
TS EN ISO
13485

Scope of the Certificate:

TS EN ISO 13485:2016

DESIGN, MANUFACTURE AND DISTRIBUTION OF

- NEUROSURGICAL PATTIES, PADS
- FIXING, SUPPORTING AND PROTECTIVE BANDS
- OPERATING ROOM LIGHT HANDLE COVER





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

TSE has issued an IQNet recognized certificate that the organization:

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.

İKİTELLİ OSB DEMİRCİLER SAN. SİT. B7 BLOK NO:157 34490 BAŞAKŞEHİR -
İSTANBUL / TÜRKİYE

has implemented and maintains a
MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM
which fulfills the requirements of the following standard:

TS EN ISO 13485:2016

Issued on: 27-08-2020
Expires on: 10-08-2023

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

Registration Number : TR-TY-022 / 17-R16



Alex Stoichitoiu

President of IQNet

Mesut Duru

Head of System Certification Group



*IQNet Partners**

AENOR Spain AFNOR Certification France APCER Portugal CISO Italy

CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil

FONDONORMA Venezuela ICONTEC Colombia Inspectia Serfiointi Oy Finland INTECO Costa Rica

IRAM Argentina JQA Japan Kfq Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland

NYCE - SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia

SIRM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

IQNet is represented in the USA by: AFNOR Certification, CISO, DQS Holding GmbH and NSAI Inc.



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNET Certificate Number :TR-TY-022/17-R16

Name and Address of the certified organization

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.

İKTİLLİ OSB DEMİRCİLER SAN. SİT. B7 BLOK NO:157 34490 BAŞAKŞEHİR - İSTANBUL /
TÜRKİYE

Scope of the Certificate

DESIGN, MANUFACTURE AND DISTRIBUTION OF

- NEUROSURGICAL PATTIES, PADS
- FIXING, SUPPORTING AND PROTECTIVE BANDS
- OPERATING ROOM LIGHT HANDLE COVER

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



TURKISH STANDARDS INSTITUTION

