



Tıbbi Cihazlar KYS
TS EN ISO/IEC 17021-1
AB-0002-YS

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE



TÜRK STANDARDLARI ENSTİTÜSÜ
bu belge ile

MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ
TEKNOLOJİ SAN. VE TİC. A.Ş.
BÜYÜKKAYACIK OSB MAH. T. ZIYAEDDİN
AKBULUT CAD. FABRİKA ÜRETİM APT. D:19 A1
SELÇUKLU
KONYA / 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.

TURKISH STANDARDS INSTITUTION
hereby certifies that the organization

MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ TEKNOLOJİ
SAN. VE TİC. A.Ş.
BÜYÜKKAYACIK OSB MAH. T. ZIYAEDDİN AKBULUT
CAD. FABRİKA ÜRETİM APT. D:19 A1 SELÇUKLU
KONYA / 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



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Konya Belgelendirme Müdürü
Konya Certification Manager

İzzet ŞEN

Belge No / Certificate No	TY-007/08/12-R16
Belge Tarihi / Date of Certificate	28.12.2023
Geçerlilik Tarihi / Valid Until	28.12.2026
Revizyon Tarihi / Date of Revision	28.12.2023
İlk Belge Tarihi / Initial Certification Date	24.10.2008

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

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



TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

EK / APPENDIX



Belge No / Certificate No: TY-007/08/12-R16

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

Belge Kapsamı:

TS EN ISO 13485:2016

- HASTA KARYOLASI-ERİŞKİNLER İÇİN
- HASTA KARYOLASI-ÇOCUKLAR İÇİN
- JİNEKOLOJİK MUAYENE MASASI
- DOĞUM YATAĞI
- ELEKTROMEKANİK SEDYE
- HİDROLİK SEDYE
- TRANSFER SEDYESİ

TASARIMI VE ÜRETİMİ

Belge Tarihi / Date of Certificate: 28.12.2023

MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ
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BÜYÜKKAYACIK OSB MAH. T. ZİYAEDDİN
AKBULUT CAD. FABRİKA ÜRETİM APT. D:19 A1
SELÇUKLU
KONYA / TÜRKİYE

Scope of the Certificate:

TS EN ISO 13485:2016

DESIGN AND PRODUCTION OF

- HOSPITAL BED-FOR ADULTS
- HOSPITAL BED-FOR CHILDREN
- TABLE FOR GYNECOLOGICAL EXAMINATION
- DELIVERY BED
- ELECTROMECHANIC STRETCHER
- HYDRAULIC STRETCHER
- TRANSFER STRETCHER



Certificate

TSE has issued an IQNet recognized certificate that the organization:

MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ TEKNOLOJİ SAN. VE TİC. A.Ş.

BÜYÜKKAYACIK OSB MAH. T. ZİYAEDDİN AKBULUT CAD. FABRİKA ÜRETİM APT. D:19 A1 SELÇUKLU
KONYA / TÜRKİYE

has implemented and maintains a
MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM
for the following scope:
Scope of the certificate is given in annex

which fulfills the requirements of the following standard:

TS EN ISO 13485:2016

Issued on: 28-12-2023

First Issued on: 24-10-2008

Expires on: 28-12-2026

Registration Number : TR-TY-007/08/12-R16



Alex Stoichitoiu
President of IQNet



İzzet ŞEN
Konya Certification Manager



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

IQNet Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela
ICONTEC Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan
KFQ Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** México **PCBC** Poland
Quality Austria Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

Certificate

Annex to IQNET Certificate Number :TR-TY-007/08/12-R16

Name and Address of the certified organization

**MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ TEKNOLOJİ SAN. VE TİC.
A.Ş.**

BÜYÜKKAYACIK OSB MAH. T. ZIYAEDDİN AKBULUT CAD. FABRIKA ÜRETİM APT. D:19 A1 SELÇUKLU KONYA / TÜRKİYE

Scope of the Certificate

DESIGN AND PRODUCTION OF

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This annex is only valid in connection with the original certificate number mentioned above.

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