

**AT-DECLARATION of CONFORMITY**

MANUFACTURER : Medikal 2000 Tıbbi Cihazlar ve İleri Teknoloji Sanayi ve Ticaret A.Ş.

ADRESS: KOS Bölgesi, T. Ziyaeddin Akbulut Cd. No:19 42300, Selçuklu/Konya/TÜRKİYE

REFERENT : Mustafa ÇİMEN

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WEB SITE: <https://www.medikal2000.com.tr/>

E-MAIL: mcimen@medikal2000.com.tr bilgi@medikal2000.com.tr

PRODUCT NAMES : Hospital Bed, Stretchers, Treatment Table, Gynecology Examination Table, Trolleys, Cabinets, Overbed Tables, Mattress, Other Products

EUDAMED SRN : TR-MF-000019533

CLASSIFICATION : Class I, Rule 1 according to MDR Regulation (EU) 2017/745

COUNCIL DIRECTIVE: Compliance has been assessed according to the procedure set out in Regulation (EU) 2017/745 of the European Parliament and of the Council, Annexes I, II, III, IV, VIII.

USED HARMONISED STANDARDS:

- TS EN 15223-1 – Medical Devices- Symbols to be used with Medical Device Labels, Labelling and Information to Supplied, Part 1: General Requirements
- TS EN 14073-2 Office furniture - Storage furniture - Part 2: Safety requirements
- TS EN 12520 Furniture - Strength, durability and safety - Requirements for domestic seating
- TS-EN 60601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds

We hereby declare that the equipment specified above conforms to the applicable sections of the Council Regulation concerning medical devices (EU) 2017/745. Any modifications made to this product without our express permission and approval shall render this declaration null and void.

This certificate of conformity is certified according to EN ISO 9001, EN ISO 13485, EN ISO 14001 and ISO 45001.

Place: Konya, Türkiye

Date: 14.08.2025

Signature

Chairman of the Board

Necip ÇİMEN

Medikal 2000
Tıbbi Cihazlar ve İleri Teknoloji
Sanayi ve Ticaret A.Ş.
B.Kavayıcı OSB Mahallesi T. Ziyaeddin Akbulut Cad.
Fabrika Üretim Apt. No:19/A1 Selçuklu / KONYA
Telefon : 0332 239 1080 Faks : 0332 239 1082
Selçuk Vergi Dairesi 611 013 0985

PRODUCT CODE	PRODUCT NAME	PRODUCT PICTURE	BASIC UDI-DI	GMDN CODE
MN-01	MECHANIC HOSPITAL - 1 Function		8697601522707	34873
MN-02	MECHANIC HOSPITAL BED - 2 Functions		8697601521809	34873
MN-03	MECHANIC HOSPITAL BED - 3 Functions		8697601522714	34873
PLUS A2	ELECTROMECHANIC HOSPITAL BED - 2 Motors		8697601520628	34870
PLUS A3	ELECTROMECHANIC HOSPITAL BED - 3 Motors		8697601520635	34870
PLUS A7	ELECTROMECHANIC HOSPITAL BED - 3 Motors		8697601520673	34870
PLUS A8	ELECTROMECHANIC HOSPITAL BED - 4 Motors		8697601520680	34870
PLUS A9	ELECTROMECHANIC HOSPITAL BED - 4 Motors with 2 Column Motors		8697601522677	34870
PLUS T	ELECTROMECHANIC HOSPITAL BED - 5 Motors with 2 Column Motors		8697601522790	34870

Medikal 2000 Tıbbi Cihazlar ve İleri Teknoloji Sanayi ve Ticaret A. Ş.

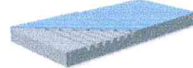
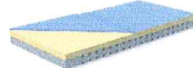
PLUS 3T	ELECTROMECHANIC HOSPITAL BED 5 Motors with 3 Column Motors		8697601522813	34870
ALARA 3M	ELECTROMECHANIC HOSPITAL BED – 3 Motors		8697601522653	37010
ALARA Y	ELECTROMECHANIC PEDIATRIC BED – 4 Motors		8697601522660	37010
RC-01	HOME CARE BED – 3 Motors		8697601522776	34870
M2-DB	DELIVERY BED – 3 Motors		8697601522806	15732
M2- DXS	DELIVERY BED – 4 Motors		8697601522318	13960
M2-T38	PATIENT STRETCHER		8697601522547	13818
HYS-01	PATIENT WASH STRETCHER		8697601522844	31092
M2-T42	OPERATION ROOM TRANSFER STRETCHER		8697601522554	35892

M2-T300	HYDRAULIC EMERGENCY STRETCHER		8697601521243	13818
M2-T700	HYDRAULIC EMERGENCY STRETCHER		8697601522561	13818
M2-T800	HYDRAULIC EMERGENCY STRETCHER		8697601522103	13818
LFT-01	PATIENT TRANSPORT LIFT- 1 Motor		8697601522851	46148
MM-01	METAL TREATMENT TABLE		8697601522721	36065
MM-02	WOODEN TREATMENT TABLE		8697601522738	36065
M20-EMM	ELECTRICAL TREATMENT TABLE – 2 Motors		8697601522820	31362
DC-02	BLOOD DONOR CAHIR – 2 Motors		8697601522752	10789
DC-03	BLOOD DONOR CAHIR – 3 Motors		8697601522769	10789

PC-01	PODIATRY CHAIR- 3 Motors		8697601522868	36065
JX-02	GYNECOLOGY EXAMINATION TABLE – 3 Motors		8697601522783	36065
JX-03	GYNECOLOGY EXAMINATION TABLE – 4 Motors		8697601522745	36065
PT-01	PATIENT TRANSPORTATION CHAIR		8697601522264	41619
BK-01	BABY COT		8697601522837	38140
CYM-01	ALUMİNYUM OVERBED TABLE			
YM-07	OVERBED TABLE			

YM-08	OVERBED TABLE			
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MM-03	PEDİATRİC EXAM TREATMENT TABLE		-	-
MA-01	DRUG TROLLEY		-	-
MA-02	DRUG AND ANESTHESİA TROLLEY		-	-
MA-03	EMERGENCY TROLLEY/CRASH CART		-	-
CEY-01	CABINET WITH OVERBED TABLE		-	-
CEY-02	CABINET WITH OVERBED TABLE		-	-
CEY-03	CABINET WITH OVERBED TABLE		-	-
CEY-04	CABINET WITH OVERBED TABLE		-	-

E-05	CHİPBOARD CABİNET		-	-
S-01	MATTRESS		-	-
S-02	MATTRESS		-	-
S-03	MATTRESS		-	-
DB-01	MONKEY BAR		With bed models : PLUS A2, A3, A7, A8, 3T, ALARA Y, ALARA 3M	-
SR-01	IV POLE		With bed models : PLUS A2, A3, A7, A8, 3T, ALARA Y, ALARA 3M	-

Place: Konya, Türkiye
Date: 14.08.2025
Signature
Chairman of the Board
Necip CİMEN


Medikal 2000
 TIBBİ CİHAZLAR VE İLERİ TEKNOLOJİ
 SANAYİ VE TİCARET A.Ş.
 B.Kayacık OSB, Mahallesi T. Ziyaeddin Akbulut Cad.
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Tel : +90 332 239 10 80 (Pbx) Faks: +90 332 239 10 82
bilgi@medikal2000.com.tr



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



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

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-ERİŞKİMLER 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
TEKNOLOJİ SAN. VE TİC. A.Ş.
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



Handwritten signature

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

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

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

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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

SERTİFİKA

(CERTIFICATE)

MEDİKAL 2000 TIBBİ CİHAZLAR VE İLERİ TEKNOLOJİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

BÜYÜKKAYACIKOSB MAH. T.ZİYAEDDİN AKBULUT CAD. NO: 19 A/1
SELÇUKLU/ KONYA/ TÜRKİYE

ISO 14001:2015

Kapsam/Scope

KARYOLA, HASTANE YATAĞI, SEDYE, İLAÇ ARABASI (PANSUMAN ARABASI, ACİL
MÜDAHALE VE ANESTEZİ ARACI), ANTİ BAKTERİYEL VE ANTİ DEKUBİT YATAK (ŞİLTE)
ÜRETİMİ VE SATIŞI, HASTANE MOBİLYASI (KOMODİN, YEMEK MASASI) TASARIMI,
ÜRETİMİ VE SATIŞI

PRODUCTION AND SALES OF BEDSTEADS, HOSPITAL BEDS, STRETCHERS, MEDICAL
CARTS (DRESSING TROLLEYS, EMERGENCY RESPONSE AND ANESTHESIA VEHICLES),
ANTI-BACTERIAL AND ANTI-DECUBITUS MATTRESSES, AND DESIGN, PRODUCTION AND
SALES OF HOSPITAL FURNITURE (BEDSIDE CABINETS, OVERBED TABLES)

EA: 23-34

Bu sertifika ile yukarıda adı geçen kuruluşun Çevre Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.
This is to certify that the above mentioned company meets the requirement of Environmental Management System.

Sertifika No / Certification Number	: 14.26.21098.2000486.U
İlk Kayıt Tarihi / Date of Initial Reg.	: 3.07.2026
Basım Tarihi / Date of Certificate	: 3.07.2026
Geçerlilik Tarihi / Date of Expiry	: 2.07.2027
Revizyon / Revision	: 000

Bu sertifika kuruluşun belgelendirme şartlarına uyması ve yılda en az 1 kez yapılacak olan gözetim denetimlerinin
başarılı geçmesi halinde üç yıllık sertifikasyon periyodu bitiş tarihine kadar geçerlidir.

This certificate is valid until the end of the three-year certification period if the organization complies with the certification
requirements and the surveillance audits to be carried out at least once a year are completed successfully.




Ravinder KAKKAR



Accredited by United Accreditation Foundation Inc. (UAF)
400 North Center DR STE 202 Norfolk VA 23502 United States of America (USA)