



AT UYGUNLUK BEYANI / EC DECLARATION OF CONFORMITY

BELGE No/CERT.No: CE-03

MIAMED MEDİKAL TEKSTİL İNŞAAT TURİZİM GIDA TİCARET VE SANAYİ LIMITED

Aşağıda imal yılı seri numarası verilen mamul/mamullerin ilk dökümanlarda tanımlandığı gibi 90/32/EEC Tıbbi Cihazlar Direktifi yönetmeliği karşılamak şekilde ürettiğimizi beyan ederiz.

WE CLEARLY DECLARE THAT OUR PRODUCT(S), GIVEN BELOW WITH SERIAL NUMBER AND PRODUCTION YEAR, MANUFACTURED IN COMPLIANCE WITH 90/32/EEC MEDICAL DEVICES DIRECTIVE, AS DEFINED IN FIRST DOCUMENTS

 **Mia Med**

Tyoe : Mia-Medical Bed Series

Model : 2 Motors Electrical Patient Bed, 3 Motors Electrical Patient Bed, 4 Motors Electrical Patient Bed, 4 Motors Intensive Care Patient Bed, 4 Motors Intensive Care Patient Bed, 4 Motors Intensive Care Patient Bed, 4 Motors Column Model Intensive Care Patient Bed,

Year of prod. : 2019

Serial No. :-

Standard No. : TS EN 60601-1:2009 , TS EN 60601-2-52:2010/AC:2011, EN 1865-1:2010+A1:2015, EN 60204-1 , TS EN ISO 13849-1,

Address : Çiftlikköy Mah. Şakir Son Caddesi Sera Park Sitesi No: 86/3 Yenışehir / MERSİN / TÜRKİYE

WAS TURKEY

Certification Manager

Ali Erdem ERTAS

01/04/2019

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Ebulula Mardin Cad. Yıldırım Oğuz Göker Sokak

Park Maya Sitesi Carlton 17 Blok Daire:9 34335 Akatlar/İstanbul



**DECLARATION OF CONFORMITY**

IN accordance with 90/32/EC Medical Devices Directive of the Council of European Union, whose purpose is providing conformity of laws, directives and administrative of documents of member countries in respect to Medical Device;

Name and Address of the Company: MIAMED MEDİKAL TEKS. İNŞ. TUR. GID. TİC. VE SAN. LTD.

Tel: +90 324 502 35 11 **Fax:** +90 324 502 35 12

Applied Directives: 90/32/EC- Medical Devices Directive

Classification and Annex Applied: Product is subject to Medical Devices Directive Class 1. Applied.

Name of Product and Types:

Electric Hospital Beds: BED-01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, MIA COMFORT BED, MIA GRANDE 1, 2, 3, 4

Women's Birthing Bed: MIA DELIVERY BED

Manual Hospital Beds: BED-15, BED-16

Pediatric Patient Care Beds: PED-1, PED-2, PED-3, PED-4

Stretchers: STR-1, STR-2, STR-3, STR-4

Baby Code: MIA BABY COT 1, 2

Examination Tables: MIA EXAMINATION COUCH 1, 2, 3

Companion Chair: ARM CHAIR BED 1, 2, 3

Front Patient Tables: OVER BEDTABLE 1, 2, 3, 4

Bedside Bedside Tables: BEDSIDE CABINET 1, 2, 3, 4, 5, 6, 7, 8

Wardrobes: SINGLE WARDROBE 1, 2, 3, DOUBLE WARDROBE 1, 2, 3

Gynecological Examination Table: GYNEC-01, 02, NEW GENERATION GYNECOLOGICALEXAMINATION COUCH

Patient Transport Trolley: PATIENT TRANSFER TROLLEY

Blood Collection Chair: BLOOD DONATION CHAIR

Mattresses: MIA S01, S02, S03, MATTERS VISCO 1, VISCO 2,

Infusion Carrier: INFUSION HOLDER 1, 2

Medicine Trolleys: MIA MED CAR 1, 2, 3, 4, 5

Patient Bed Head Units: MIA HEAD UNITS 1, 2, 3

Patient Bed Head Units Wood: MIA HEAD UNITS 4, 5, 6

Color Chart: MIA COLOR OPTIONS, MIA WOOD COLOR OPTIONS

Accessories: MIA LIFTING POLE (POWDER PAINTED), MIA LIFTING POLE (CHROME PAINTED), MIA IV POLE,

MIA BED EXTENTION, MIA BED EXTENTION 2, MIA STAIONARY HEADBOARD, MIA X RAY CASSET CARRIER,

MIA NURSE HANDSETS SHELF, MIA DEFRIBILATOR SHELF, MIA OXYGEN CYLINDER HOLE, MIA URINE BAG HOLDER,

MIA MANUAL CPR

Declaration:

Our company manufactures the products stated above in accordance with the requirements of the current EN 980-1996/A1 (Graphs and Symbols Used on labels) EN 1401 (Information provided with the Product by Manufacturer) **ISO 13485:2016** Medical Devices Quality Management System.

Used Standards;

The mentioned products are complying with the requirements of the following **standards;** EN 60601-1:2006/A1:2013 EN 60601-1-2:2007 EN 60601-1-6:2010, IEC60601-2-38, EN 60601-2-52: 1-2010

The products described above were subjected to initial type experiments by Manufacturer and factory manufacture control was carried out by regular tests.

Date of Issue 01.06.2023

General Manager;

 **Mia Med**

MEDİKAL TEKSTİL İNŞ. TUR. GID. TİC. VE SAN. LTD. ŞTİ.
Çiftlikköy Mah. Şakir Son Caddesi Sera Park Site No: 86/3
Yenişehir / MERSİN T. 0324 502 35 11
İSTİKLAL V.D. 021 007 6569

CERTIFICATE OF REGISTRATION



This is to Certify that the Management System of

MIAMED MEDİKAL TEKSTİL İNŞAAT TURİZİM GIDA TİCARET VE SANAYİ LİMİTED

ÇİFTLİKKÖY MAHALLESİ ŞAKİR SON CADDESİ SERA PARK SİTESİ
NO: 86 / 3 YENİŞEHİR / MERSİN / TÜRKİYE

has been found to conform to the Medical Devices – Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope of operations:

MANUFACTURE OF FURNITURE, ARMCHAIR, CHAIR AND THEIR PARTS FOR
MEDICAL, SURGICAL, DENDISTRY AND VETERINARY, MEDICAL, SURGICAL AND
LABORATORY STERILE DEVICES

TIBBİ, CERRAHİ, DIŞÇILIK VE VETERİNERLİKLE İLGİLİ MOBİLYA, KOLTUK,
SANDALYE VE BUNLARIN PARÇALARI İLE TIBBİ, CERRAHİ VE LABORATUVAR
STERİL CİHAZLAR İMALATI

Certificate No.: TR58353H

Date of initial registration:	Date of this Certificate:	Sur. audit on or before/ Certificate expiry:	Recertification Due:
12 January 2021	12 January 2021	11 January 2022	11 January 2024

This Certificate remains valid subject to satisfactory surveillance audits.



Emmanuel

Emmanuel ADEMOSU
Director

For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search_certified_client.php
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Web :- www.staunchlyservices.com

E-mail :- info@staunchlyservices.com

Phone :- +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683





Sertifika

CERTIFICATE

MIAMED MEDİKAL TEKSTİL İNŞAAT TURİZİM GIDA TİCARET VE SANAYİ LİMİTED ŞİRKETİ

ÇİFTLİKKÖY MAHALLESİ ŞAKİR SON CADDESİ SERA PARK SİTESİ
NO: 86 / 3 YENİŞEHİR / MERSİN / TÜRKİYE

ISO 9001:2015

Kapsam/Scope

TIBBİ, CERRAHİ, DİŞÇİLİK VE VETERİNERLİKLE İLGİLİ MOBİLYA, KOLTUK,
SANDALYE VE BUNLARIN PARÇALARI İLE TIBBİ, CERRAHİ VE LABORATUVAR
STERİL CİHAZLAR İMALATI

MANUFACTURING OF FURNITURE, ARMCHAIR, CHAIR AND THEIR PARTS FOR
MEDICAL, SURGICAL, DENDISTRY AND MANUFACTURE OF MEDICAL, SURGICAL
AND LABORATORY STERILE DEVICES

Bu sertifika ile yukarıda adı geçen kuruluşun Kalite Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

This is to certify that the above mentioned Company meets the requirement of Quality Management System.

Belge NO / Certification Number	: MTS-17799
İlk Kayıt Tarihi / Date of Initial Reg.	: 3.12.2020
Basım Tarihi / Date of Certificate	: 3.12.2020
Geçerlilik Tarihi / Date of Expiry	: 2.12.2021
Yeniden Belgelendirme Tarihi / Date of Recertification	: 2.12.2023

Operasyon Müdürü / Operation Manager



sigmacert
ULUSLARARASI BELGELENDİRME
EĞİTİM VE TEST HİZMETLERİ LTD.ŞTİ.

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