

CERTIFICATE

MİAMED MEDİKAL TEKSTİL İNŞAAT TURİZM GIDA TİCARET VE SANAYİ LİMİTED ŞİRKETİ

ÇİFTLİKKÖY MAH. ŞAKİR SON CAD. SERA PARK SİT. NO:86/3 YENİŞEHİR / MERSİN / TÜRKİYE

Has been assessed and found to Comply with the Requirements of: Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to: Kalite Yönetim Sistemi:

PRODUCTION OF HOSPITAL BEDS, FURNITURE, ARMCHAIRS, CHAIRS AND PARTS RELATED TO MEDICAL, SURGICAL, DENTISTRY AND VETERINARY AND MEDICAL, SURGICAL AND LABORATORY STERILIZATION DEVICES

TIBBİ, CERRAHİ, DİŞÇİLİK VE VETERİNERLİKLE İLGİLİ HASTANE YATAKLARI, MOBİLYA, KOLTUK, SANDALYE VE PARÇALARI İLE TIBBİ, CERRAHİ VE LABORATUVAR STERİLİZASYON CİHAZLARI İMALATI

> Certificate Number: QMS-0101360 Belge Numarası: QMS-0101360

Initial Certification Date: 08.09.2021 İlk Belgelendirme Tarihi: 08.09.2021

Certification Period: 3 Years Belgelendirme Periyodu: 3 Yıl





MSCB-135

Cartificata Validity Data: 07 00 2023

Certificate Validity Date: 07.09.2023 Belge Geçerlilik Tarihi: 07.09.2023





IQR Sertifikasyon Onayı

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DECLARATION OF CONFORMITY

IN accordance with 93/42/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: 93/42/EC-Medical Devices Directive Classification and Annex Applied: Product is subject to Medical Devices Directive Class 1. Applied. Name of Product and Types: Electrical Hospital Bed : BED-1,BED-2,BED-3,BED-4,BED-5,BED-6,BED-13,BED-8,BED-14 Women's Birthing Bed : MIA 02-S JULIETTE Home Care Beds: M-SEATBED, M-RISEBED, M-COMFORT, M-ECO, M-RISEBED PLUS Manual Hospital Beds :BED-15, BED-16, MIA HYDRAULIC HOSPITAL BED Pediatric Patient Care Beds: PED-1, PED-3, PED-4 Stretchers: STR-1,STR-2,STR-3,STR-4,STR-5,MRI COMPLATIBLE STRETCHERS Baby Code: BABY COT 1,2 **Examination Table**: 2 MOTORS EXAMINATION TABLE, MIA 3086, MIA EXAMINATION COUCH SERIES Companion Chairs : ARM CHAIR SERIES 1-2 MIAMC-01 MIAMC-02 MIAMC-03 MIAMC-04 MIAMEC-05 Front Patient Tables : OVERBED TABLES 1,2,3,4,5 Bedside Tables: BEDSIDE CABINETS 1,2,3,4,5,6,7,8,9,10,11,12,MIA OVERBED TABLE WITH BEDSIDE CABINET 1,2,3,SPECIAL DESIGN Gynecological Examination Table : MIA GT-01, MIA GYNEC TABLE 2, MIA GYNEC TABLE 3, MIA NEW GENERATION GYNECLOGICAL EXAMINATION TABLE Patient Transfer Trolley : MIA PATIENT TROLLEY, MIA PLUSE, MIA WHEEL CHAIRS Blood Collection Chairs : MB-05, MIA BLOOD DONATION CHAIR -01 Mia Mattress: S-01,S-02,S-03,S-FX 01,S-FX02 Infusion Carrier & Folding Screen: MIA 100, MIA 101, MIA 3072 Medicine Trolleys : MIA CAR 01,02,03,04,05,MEDICAL RECORD TROLLEY MIA 3109 MEDICATION CABINET: MIA-3089 Electrical Chairs: MB-06,MIA-09,ELITE,ENT,ENT2,MDR-2,MDR-3,PT,PT1,MIA-10,FS1,GP-04 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 CYLENDER 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/ Al (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/ Al: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 aut by regular tests.

Date of Valid 01.06.2025



