



AT UYGUNLUK BEYANI / EC DECLARATION OF CONFORMITY

BELGE NO/CERT.NO: CE-03

MIAMED MEDİKAL TEKSTİL İNŞAAT TURİZİM GIDA TİCARET VE SANAYİ LİMİTED

Aşağıda imal yılı seri numarası verilen mamul/mamullerin ilk dökümanlarda tanımlandığı gibi 93/42/EEC Tıbbi Cihazlar Direktifi yönetmeliği karşılacak şekilde ürettiğimizi beyan ederiz.

WE CLEARLY DECLARE THAT OUR PRODUCT(S), GIVEN BELOW WITH SERIAL NUMBER AND PRODUCTION YEAR, MANUFACTURED IN COMPLIANCE WITH 93/42/EEC MEDICAL DEVICES DIRECTIVE, AS DEFINED IN FIRST DOCUMENTS



Mia Med

Type : 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 : Çiğli Köy Mah. Şakir Son Caddesi Sera Park Sitesi No: 86/3 Yenişehir / MERSİN / TÜRKİYE

WAS TURKEY

Certification Manager
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01/04/2019

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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. GİD. 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

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

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 DEFIBRILATOR 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 aut by regular tests.

Date of Valid 01.06.2025

General Manager



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