CE

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

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 Yenişehir / MERSİN / TÜRKİYE

WAS TURKEY
Certification Manager
Ali Erdem ERTAS
01/04/2019

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CERTIFICATION BODIES

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Mia Med

MIAMED MEDİKAL TEKS. İNŞ. TUR. GID. TİC. VE SAN. LTD.
Çiftlikköy Mah. Şakir Son Caddesi Sera Park Sitesi No: 86/3 Yenişehir / MERSİN / TÜRKİYE
+90 324 502 35 11 +90 324 502 35 12
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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:

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 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/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 Valid 01.06.2023

General Manager

Mia Med
MEDİKAL TEKSTİL İNŞ. TURZ. SIDA TİC. VE SAN. LTD. ŞTİ.
Çiftlikköy Mh. Şakir Son Cd. Sera Park Sit. No: 86/3
Yenişehir / MERSİN T. 0324 502 35 11
İSTİKLAL V.D. 621 097 6569

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

Certificate Validity Date: 07.09.2022
Belge Geçerlilik Tarihi: 07.09.2022

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com

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 13485:2016

Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar 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: 2021/MDQMS/10446
Belge Numarası: 2021/MDQMS/10446

Initial Certification Date: 08.09.2021
İlk Belgelendirme Tarihi: 08.09.2021

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 07.09.2022
Belge Geçerlilik Tarihi: 07.09.2022

ACCREDITED
Management Systems
Certification Body
MSCB-135

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