

MOVEE 1.0 — Patient Transport Stretcher

- Backrest adjustment with gas spring
- Trendelenburg and reverse trendelenburg adjustment assisted by hydrolic with manual control
- Foldable side rails
- Cross lockable castors
- Electorstatic painted metal frame
- Plastic crash bumpers
- Removable, washable at 95º, fire retardant mattress cover.

Length: 200 cm

Width: 80 cm

Castor Diameter: 15 cm

Safe Working Load: 200 kg

MEYSA TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.
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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: MEYSA TIBBI CIHAZLAR SAN VE TIC A.S.

Tel: +90 352 5013 16 6 Fax: +90 352 503 16 61

Place and Address of Manufacture: OSB. 16.Cad No:73 Melikgazi Kayseri / TURKEY

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:

Patient and ICU Beds: PIONEER CLW, CL, 4, 4.3PLUS, 4.2CARE, 4.1TREND, 3, 2, ELITE CL, 4.3 PLUS, 4, 3, 2 GRANDE CL, 4, 3, 2, DUO

Manual Patient Beds: PRIMITIVE 3,2

Stretchers: MOVEE2.1, MOVEE 2.0, DYNAMIC 2.0, MOVEE VERSUS

Gynecological Ex. Table: Mathercare 2

Pediatric Bed: JUNIOR 4, 3, 2, JUNIOR, JUNIOR ELITE

Baby Cot: NICE 1, NICE 2

Examination Table: Diagno 01,02,03

Patient Bed Side Cabinets: SERA 1,2,3,4,5,6,7,8

Patient Overbed Table: MIRACH 1,2,3

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 13485:2003 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 01.06.2018

General Manager





AT UYGUNLUK BEYANI / EC DECLARATION OF CONFORMITY

BELGE NO/CERT.No: CE-03

MEYSA TIBBİ CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ

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





Tyoe : Pioneer

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.

Grande 2,3,4,CL, Junior 2,3,4, Elite 2,3,4

Year of prod. : 2021

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,

Addres : ORGANIZE SAN. 16. CD. NO: 73

WAS TURKEY
Certification Manager
Ahmet YILDIKIM
06/03/2021

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ACCREDITED CERTIFICATION BODIES

ACCREDITATION STANDARD NO



CERTIFICATE

MEYSA TIBBİ CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ

KAYSERİ OSB MAH. 16 CAD. NO:73 MELİKGAZİ / KAYSERİ / 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

DESIGN AND PRODUCTION OF HOSPITAL FURNITURES, MEDICAL BED AND PATIEND BED

HASTANE MOBÎLYALARI, MEDÎKAL YATAK VE HASTA YATAĞI TASARIMI VE ÜRETİMİ

> Certificate Number: 2021/MDQMS/10256 Initial Certification Date: 26.05.2021 Belge Numarası: 2021/MDQMS/10256

Certification Period: 3 Years Belgelendirme Periyodu: 3 Yıl İlk Belgelendirme Tarihi: 26.05.2021

Certificate Validity Date: 25.05.2022 Belge Geçerlilik Tarihi: 25.05.2022





Management Systems **Certification Body**

MSCB-135





IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

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