

MOTHERCARE 3

3 MOTORLU JİNEKOLOJİK MUAYENELER MASASI

MOTOR GYNECOLOGICAL EXAMINATION COUCH

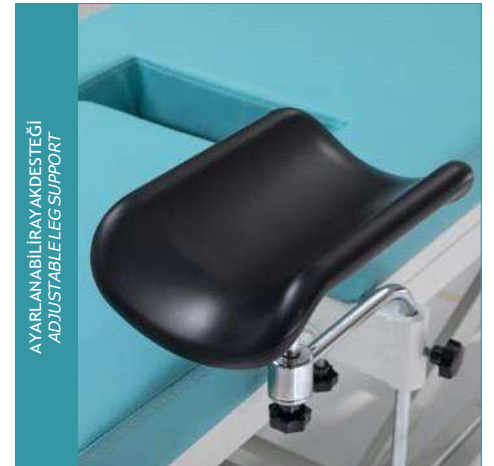


TEKNİK ÖZELLİKLER

- Elektronik motoryardımlı ile yükseklik ve başucu hareketi.
- Trendelenburg, terstrendelenburg pozisyonları.
- Yatak platform uzatma kiti.
- Ayarlanabilir ve çıkartılabilir PU baldır destek aparatları
- Paslanmaz çelik yan destek korkulukları
- Paslanmaz çelik çıkarılabilir atık küveti.
- Çapraz kilitlenebilir plastik yapıda tekerler.
- Antistatiktekerler. (merkezi ve doğrusalkilit) (Opsiyonel)
- Elektrostatik boyalı metal aksam.
- Elektrostatik termal sprey metal çerçeve (Opsiyonel).
- Kolay temizlenebilir, su geçirmez ve anti bakteriyel döşeme.
- Yüksekliği ayarlanabilir paslanmaz çelik, serum askısı.
- 24V akü ile kesintisiz çalışabilme. (Opsiyonel)
- IPX4 elektronik sistem.

TECHNICAL DETAILS

- Electrical operated backrest and height adjustment.
- Electrical operated trendelenburg, reverse trendelenburg position
- Bed extension kit.
- Adjustable and removable PU leg support
- Stainless steel side supports
- Stainless steel removable container for disposables
- Cross lockable castors.
- Central and directional lockable castors. (Optional)
- Electrostatic painted metal frame.
- Electronic thermal spray metal frame (Optional).
- Easy cleanable, water resistant anti microbial upholstery.
- Height adjustable stainless steel IV pole.
- Battery Backup. (Optional)
- IPX4 standard electronic system.



EBAT / DIMENSIONS

• Uzunluk / Overall Length	Overall	: 222 cm
• En / Overall Width		: 82 cm
• Yükseklik / Height		: 51-82 cm
• Trendelenburg / Trendelenburg		: 10°
• Ters Trendelenburg / Reverse Trendelenburg		: 10°
• Sirt kısmı (Maximum) / Backrest Angle (Max.)		: 70°
• Teker Çapı / Castor Diameter		: 12,5 cm
• Yatak Alt Boşluğu / Under Bed Clearance		: 15 cm
• Güvenli Çalışma Kapasitesi / Safe Working Load		: 190 kg
• (Aksesuarlar dahil) / (With Accessories)		

ELEKTRONİKLER / ELECTRICAL DATA

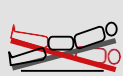
• Güç Girişi / Power In	: 1.5 A max. 230VAC 50-60 Hz
• Elektrik Çarpmasına Karşı Koruma / Electrical Shock Protection	: Class I, Type B
• Su Sızmasına Karşı Koruma / Liquid Ingress Protection	: IPX4 - IPX6
• Akü / Batteries	: 2x 12V Series, Connected, Sealed, Rechargeable, Lead/Acid gel, 1.2 amp hrs.



Sirt Hareketi
Backrest



Yükseklik
High/Low



Düz Trendelenburg
Trendelenburg



Ters Trendelenburg
Reverse Trendelenburg

MOTHERCARE 3

3 MOTORLU JİNEKOLOJİK MUAYEN MASASI
3 MOTORSGYNECOLOGICALEXAMINATION COUCH



Yükseklik / High Low



Sirt Hareketi / Backrest



Trendelenburg / Trendelenburg

MOTHERCARE 3



MEYSA TIBBİ CİHAZLAR SAN. ve TİC. A.Ş.

O. S. B. 16.Cad. No :73 Melikgazi / KAYSERİ / TÜRKİYE

+90 352 503 16 60

www.meissa.com.tr

+90 352 503 16 61

info@meissa.com.tr

To: Whom It May Concern

Date: 05.06.2023

Authorization

We, Company-manufacturer MEYSA TIBBİ CİHAZLAR SAN VE TIC A.S. located at Organize Sanayi Bölgesi 16.

Cadde No:73 Melikgazi Kayseri ,TURKIYE, hereby appoint following company:

F.C.P.C. "DataControl" S.R.L.,

17/6, N.Testimiteanu street,

MD-2025, Chişinău, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. .

Sansel SAGIR
General Manager





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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 TIBBİ CİHAZLAR SAN VE TİC A.S.

Tel: +90 352 5013 16 60 **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:

Examination Tables & Beds:

Diagno 01, Diagno 02, Diagno 04, Diagno 04

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

Managing Director





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As MEYSA TIBBİ CİHAZLAR SAN. VE TİC A.Ş., we declare that the following products are in compliance with the provisions of the Council Directive MDR- 2017/745 for medical devices. All supporting documents are stored within the manufacturer. We declare that we will fulfill the obligations imposed by the quality system and that we will maintain the quality system adequately and effectively.

Manufacturer: MEYSA TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

SRN NUMBER: TR-MF-000024429, MEYSA TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.

**Manufacturer Address: Tacettin veli mah. Halit Narin Cad. Bahadır Plaza apt. no:7/11
MELİKGAZI/KAYSERİ/TURKEY**

Product information: Check the Attached Product List.

Directives: MDR(EU) 2017/745- Medical Device Regulation

Classification: Class-I Non Sterile Products - Annex VIII

Conformity Assessment: Annex IV Declaration of conformity (Annex II & Annex III)

ŞANSEL SAĞIR

General Manager

30.05.2022

KAYSERİ/ TÜRKİYE



Primary Product Its number	Name of the product	TEMEL UDI-DI NUMBER
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86816723878426	MIP 101 INFUSION HOLDER	868358388348R4
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86816723878907	DONEE 01 BLOOD DONATION CHAIR	868358388348R4
86816723878020	NİCE 2 BABY COT	868358388348R4
86816723878068	MOTHERCARE 3 GYNECOLOGICAL EXAMINATION COUCH	868358388348R4
86816723878013	NİCE 1 BABY COT	868358388348R4
86816723878037	SUNRISE DELIVERY BED	868358388348R4
86816721878039	PIONEER 4.3 PLUS 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816721878336	PIONEER CLW 4 MOTORS COLUMN INTENSIVE CARE PATIENT BED WITH WEIGHT SCALE	868358388348R4
86816721878237	PIONEER 3 3 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816721878282	PIONEER CL 4 MOTORS COLUMN MODEL INTENSIVE CARE PATIENT BED	868358388348R4
86816723890077	GRANDE CL 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723891074	GRANDE 4 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723891876	GRANDE 3 3 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723891371	GRANDE 3.1 Trend 3 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723891173	PIONEER 4.1 Trend 4 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723889170	PIONEER 4.2 Care 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723989177	PIONEER 2 2 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723989986	PIONEER 4 4 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723981003	PEDI03 3 MOTORS PEDIATRIC ELECTRICAL PATIENT BED	868358388348R4
86816723981010	PRIMITIVE 2 2 ADJUSTMENTS MANUEL PATIENT CARE BED	868358388348R4
86816723981027	PRIMITIVE 3 3 ADJUSTMENTS MANUEL PATIENT CARE BED	868358388348R4
86816723981034	DUO 2 2 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723981041	ELİTE 2 2 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723981058	ELİTE CL 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723981065	ELİT 3 3 MOTORS ELECTRICAL PATIENT BED	868358388348R4
86816723981072	ELİT 4 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723981089	ELİT 4.3 Plus 4 MOTORS INTENSIVE CARE PATIENT BED	868358388348R4
86816723981119	ELİT JUNIOR 3 MOTORS ELECTRICAL PEDIATRİC PATIENT CARE BED	868358388348R4
86816723981225	JUNIOR PEDIATRİC PATIENT BED	868358388348R4
86816723981232	JUİÖR 3 3 MOTORS PEDIATRİC PATIENT CARE BED	868358388348R4
86816723981249	JUNIOR 4 4 MOTORS ELECTRICAL PEDIATRIC INTENSIVE PATIENT CARE BED	868358388348R4
86816723981256	DİAGNO 01 EXAMINATION CHOUCH	868358388348R4
86816723981263	DİAGNO 02 EXAMINATION CHOUCH	868358388348R4
86816723981287	DİAGNO 03 EXAMINATION CHOUCH	868358388348R4
86816726554327	MOTHER CARE 2 2 MOTORS GYNECOLOGICAL EXAMINATION COUCH	868358388348R4
86816726554358	DYNAMIC 2.0 GENERAL PURPOSE PATIENT STRETCHER	868358388348R4
86816726554907	MOVEE 2.0 PATIENT IMMEDIATE TREATMENT STRETCHER	868358388348R4
86816726554983	MOVEE 2.1 PATIENT IMMEDIATE TREATMENT STRETCHER	868358388348R4
86816726554976	MOVEE VERSUS OPERATION ROOM TRANSFER STRETCHER	868358388348R4
86816723890008	PIONEER 3.1 Trend 3 MOTORS PATIENT CARE BED	868358388348R4
86816723890701	IMPULSE STACKABLE WHEELCHAIR	868358388348R4

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 46 din 09.06.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: Examination Bed

Model: DIAGNO 04

Product: Gynecological Examination Couch

Model: MOTHERCARE 3

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

Data **09.06.2023**

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Product: Examination Bed

Model: DIAGNO 04

Product: Gynecological Examination Couch

Model: MOTHERCARE 3

Sunt autentice și corespund realității

Alexandru Grabazei, director

Semnătura

Data: **09.06.2023**





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to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. .

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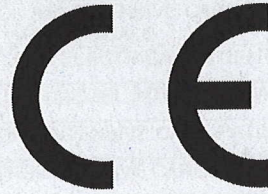
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MELİKGAZI/KAYSERİ/TURKEY**

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Conformity Assessment: Annex IV Declaration of conformity (Annex II & Annex III)



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General Manager

30.05.2022

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Date of Issue 01.06.2018

Managing Director



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