

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. TR-99 din 15.12.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Puskin 60/1,
of. 4, tel./fax: 022-22-03-02, [e-mail triumf.motiv@mail.ru](mailto:triumf.motiv@mail.ru), 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:

Denumire generică (denumirea dispozitivului)	Modelul
Patient and ICU Beds (PIONEER SERIES)	PIONEER 4.2 W

Se anexează următoarele acte:
DECLARAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Data 15.12.2023

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	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: TRIUMF MOTIV SRL, cu
sediul or. Chișinău str. Puskin 60/1, of.4,

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:

Denumire generică (denumirea dispozitivului)	Modelul
Patient and ICU Beds (PIONEER SERIES)	PIONEER 4.2 W

Sunt autentice și corespund realității.

Numele, prenumele și funcția Jighili Tatiana, Administrator
Semnătura _____

Data 15.12.2023



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

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

+90 352 503 16 60

+90 352 503 16 61

www.meissa.com.tr

info@meissa.com.tr

LETTER OF AUTHORIZATION

Date: June 10th, 2023

To Whom It May Concern:

Hereby, we

Company Name: MEYSA TIBBİ CİHAZLAR

Address: OSB 16. CADDE NO:73 MELİKGAZI /KAYSERİ

Phone number: +90 352 503 16 60

Certify that:

Triumf Motiv SRL

Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand MEISSA in your country.

This letter of authorization remains valid for five years, starting from June 20.2023 and expiring on March 09, 2028.

Name: A. FURKAN OZSOY

Title: GENERAL MANAGER

Signature:

**MEYSA TIBBİ CİHAZLAR
SAN. VE TİC. A.Ş.
OSB 16. Cadde No. 73
Melikgazi / KAYSERİ
Mimarsinan VV 030 061 0992**

**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 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, 4.3PLUS, 4.2CARE, 4.2 W, 4.2LW 4.1 TREND, 3.1 , 2, DUO 2, PRIMITIVE 1,2,3

Stretchers: MOVEE 2.0 NW, DYNAMIC 3.0 , DYNAMIC 2.0, DYNAMIC 1.0 , MOVEE VERSUS, HYDRAULIC SHOWER STRETCHER

Gynecological Ex. Table: MOTHERCARE 2, MOTHERCARE 3

Pediatric Bed: JUNIOR 4, 3, 2, JUNIOR

Delivery Bed : SUNRISE

Chair: DONEE 01 , 02, 03

IV Stand: MIP 100, MIP 101

Armchair Bed: Relaxia 01,02,03,04,05

Examination Table: Diagno 01,02,03

Patient Transport : Hercules

Trolley: Tena 01, Tena 02, Tena 03, Tena

04, Emergency Trolley

Patient Bed Side Cabinets: SERA

1,2,3,4,5,6,7,8,9,10,11,12

Patient Overbed Table: MIRACH 1,2,3,4,5

Baby cots : NICE 01,02

Mattress : Smooth ST , 01 , 02 , FX 01 , FX 02 , FX 03

Wardrobe : Bien 01 , 02 , Beta 01 , 02, Bona 01 , 02

Accessories : Lifting pole, iv pole, A4 sheet holder, oxygen bottle holder , urine bag basket , defibrillator tray, nurse control, hand control , length extension , traction frame,

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 01.01.2023

General Manager





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;

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04, Emergency Trolley

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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 01.01.2023

General Manager





CERTIFICATE

**MEYSA TIBBİ CİHAZLAR
SAN. VE TİC. A.Ş.**

**KAYSERİ OSB MAH. 16 CAD. NO:73
MELİKGAZI / KAYSERİ / 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:*

**DESIGN, PRODUCTION AND AFTER-SALES SERVICES OF HOSPITAL
FURNITURE, MEDICAL BED AND PATIENT BED**

**HASTANE MOBİLYALARI, MEDİKAL YATAK VE HASTA YATAĞI
TASARIM, ÜRETİM VE SATIŞ SONRASI HİZMETLERİ**

**Certificate Number: QMS-0112231
Belge Numarası: QMS-0112231**

**Initial Certification Date: 14.07.2023
İlk Belgelendirme Tarihi: 14.07.2023**

**Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl**

**Certificate Validity Date: 13.07.2024
Belge Geçerlilik Tarihi: 13.07.2024**

IQR Sertifikasyon Onayı



ACCREDITED
Management Systems
Certification Body
MSCB-135

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

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

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, PRODUCTION AND AFTER-SALES SERVICES OF HOSPITAL
FURNITURE, MEDICAL BED AND PATIENT BED**

**HASTANE MOBİLYALARI, MEDİKAL YATAK VE HASTA YATAĞI
TASARIM, ÜRETİM VE SATIŞ SONRASI HİZMETLERİ**

Certificate Number: 2023/MDQMS/10992
Belge Numarası: 2023/MDQMS/10992

Initial Certification Date: 10.03.2023
İlk Belgelendirme Tarihi: 10.03.2023

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 09.03.2024
Belge Geçerlilik Tarihi: 09.03.2024

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

4

MOTOR

PIONEER 4.2 W

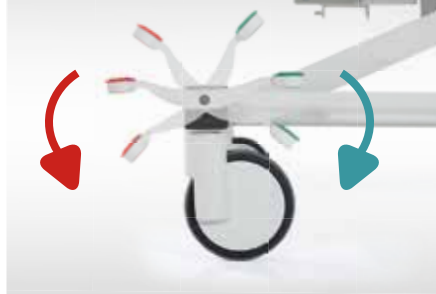
TARTILI YOĞUN BAKIM HASTA KARYOLASI
INTENSIVE CARE PATIENT BED WITH WEIGHT SCALE

TEKNİK ÖZELLİKLER

- Gelişmiş entegre tartı sistemi.
- Elektronik motor yardımı ile yükseklik, başucu ve ayakucu hareketi.
- Trendelenburg, ters trendelenburg, fowler ve vasküler pozisyonları.
- Hasta el kumandası.
- Hemşire kontrol ünitesi.
- Korkuluk kumandası. (Opsiyonel)
- Elektronik CPR tuşu.
- Otomatik kayma sistemine sahip başucu
- Auto contour.
- Hijyenik dizayna sahip plastik (PP), kilitlenebilen ve gizlenebilen yan korkuluklar.
- Kolay sökülüp takılabilen ABS plastik muhafazalı, profil şase.
- Hijyenik dizayna sahip plastik (PP) kolay sökülüp takılabilen başlıklar.
- Antistatik tekerler.(merkezi ve doğrusal kilit)
- Elektrostatik boyalı metal aksam.
- Yüksekliği ayarlanabilir paslanmaz, serum askısı
- Diz hareketlerini kolay ayarlayabilme özelliği.
- Plastik çarpma tamponları.
- 24V akü ile kesintisiz çalışabilme.
- Sırt kısmında mekanik CPR.
- Başucu ve ayakucu köşelerinde aksesuar yuvası
- Yatağın sağ ve sol kısmında 3'er adet drenaj askısı.
- Sırt açış göstergesi.
- Karyola açış göstergesi.
- Tek tuşla cardiac chair (Sandalye) pozisyonu.
- Tek tuşla shock pozisyonu.
- Tek tuşla semi fowler pozisyonu.
- Tek tuşla yataktan çıkış pozisyonu.
- Tek tuşla muayene pozisyonu.
- İstem dışı kullanımları önlemek için hemşire kumandasında aktivasyon tuşu.
- Yatak platform uzatması 18 cm (Opsiyonel)
- X-Ray geçirgen sırt ve kaset yuvası.
- 5. teker vasıtası ile kolay manevra imkanı. (Opsiyonel)
- IPX4 elektronik sistem.

TEKNİK DETAYLAR

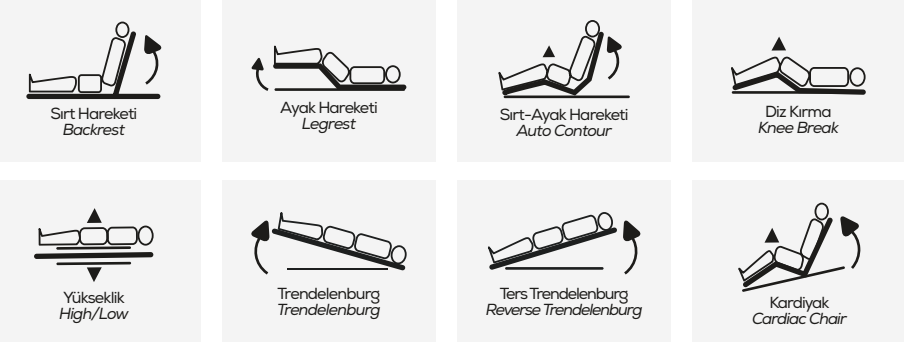
- Comprehensive integrated weighing system.
- Electrical operated backrest, height and legrest adjustment.
- Electrical operated trendelenburg, reverse trendelenburg, fowler and vascular position.
- Patient handset.
- Nurse control unit.
- Control unit built-in siderails. (Optional)
- Auto-CPR.
- Retracting backrest for advanced comfort, less pressure.
- Auto contour.
- Hygienic design (PP), lockable and tuck away side rails.
- Profile frame with easy removable ABS plastic covers.
- Removable head and foot ends.
- Central and directional lockable castors.
- Electrostatic painted metal frame.
- Height adjustable stainless IV pole.
- Easy adjustable knee break position.
- Plastic crash bumpers.
- Battery Backup.
- Dual sided manual CPR at backrest.
- Comprehensive range of accessories socket at corners.
- 3 drainage hangers on the right and left side of the bed.
- Angle gauge for back.
- Angle gauge for bed.
- Cardiac chair position with one button.
- Shock position with one button.
- Semi-Fowler position with one button.
- Bed exit position with one button.
- Examination position with one button.
- Activation key at remote control to prevent any undesired positions.
- Bed extension 18 cm (Optional)
- X-Ray translucent backrest and cassette carrier.
- Fifth wheel for easy steering.(Optional)
- IPX4 standard electronic system.

HEMŞİRE KONTROL ÜNİTESİ
NURSE CONTROL UNITHASTA EL KUMANDASI
PATIENT HANDSETTARTI GÖSTERGESİ
SCALE INDICATORMERKEZİ FREN SİSTEMİ
CENTRAL LOCK

ELEKTRONİK VERİLER / ELECTRICAL DATA

- Güç Girişi / Power In : 1.5 A max. 230V AC 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.

RENK KARTELESİ / COLOR OPTIONS



Uzunluk
Overall Length
216 cm

En
Overall Width
102 cm

Yükseklik (Siltisiz)
Height Range
(Without mattress)
42 - 84 cm

Trendelenburg
Trendelenburg
0°- 16°

Ters Trendelenburg
Reverse Trendelenburg
0°- 16°

Sırt Kısmı (Max.)
Backrest Angle (Max.)
70°

Ayak Ucu Kısmı (Max.)
Legrest Angle (Max.)
35°

Teker Çapı
Castor Diameter
15 cm

Yatak Altı Boşluğu
Under Bed Clearance
15 cm

Güvenli Çalışma Kapasitesi
Safe Working Load
230 kg

4

MOTOR

PIONEER 4.2 W

TARTILI YOĞUN BAKIM HASTA KARYOLASI
INTENSIVE CARE PATIENT BED WITH WEIGHT SCALE

• Ürün görselleri seçilen aksesuarlar ve opsiyonlara göre farklılık gösterebilir.
• Product images may vary according to selected accessories and options.

Low Bed



Sirt Hareketi / Backrest



Trendelenburg / Trendelenburg



Kardiyak / Cardiac Chair

