ECHIPAMED
P L U S
Moldova, MD - 2001, Chisinau, str. Valea Trandafirilor 24 "B", of. 2-7
tel. +373 (22) 234 349, 234 225; fax +373 (22) 234 225
e-mail: office@echipamed.com, info@echipamed.com

Nr. 12-23
din 03.07.2023

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

Solicitantul **„Echipamed-Plus" SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, 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:

Nr	Denumire	Denumire comercială	Model
1	Pat pentru examinare		MIA 3086
2	Brancarda		STR-3
3	Brancarda		STR-4
4	Pat functional		MIA 06-S RED LINE
5	Pat pediatric		BED-15
6	Fotoliu ginecologic		MIA GT-01

Se anexează următoarele acte:

1. Declarații de conformitate CE.
2. Declarații de la producător privind desemnarea reprezentantului.
3. Declarație pe proprie răspundere.

Data 03.07.2023 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	

ECHIPAMED
P L U S
Moldova, MD - 2001, Chisinau, str. Valea Trandafirilor 24 "B", of. 2-7
tel. +373 (22) 234 349, 234 225; fax +373 (22) 234 225
e-mail: office@echipamed.com, info@echipamed.com

Nr. F/N
din 03.07.2023

Către Agenția Medicamentului
și Dispozitivelor Medicale

Declarație pe proprie răspundere

Solicitant: **„Echipamed-Plus" SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, declar pe proprie răspundere, cunoscînd prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificare dispozitivului medical:

Nr	Denumire	Denumire comercială	Model
1	Pat pentru examinare		MIA 3086
2	Brancarda		STR-3
3	Brancarda		STR-4
4	Pat functional		MIA 06-S RED LINE
5	Pat pediatric		BED-15
6	Fotoliu ginecologic		MIA GT-01

Sunt autentice și corespund realității.

Director Valeiu Iurchevici

Semnătura _____

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

Mia Med

0 324 502 35 11 0 532 344 72 41
info@mia-medical.com www.mia-medical.com
İstemihan Talay Street Sera Park Build.86/3
Yenisehir / Mersin,

Authorization Letter No.1

Date: JUNE 28, 2023

By the present authorization letter **No.1,** company on behalf of MIAMED MEDİKAL TEKSTİL İNŞAAT TURİZİM GIDA TİCARET VE SANAYİ LİMİTED (further PRINCIPAL) authorizes " ECHIPAMED PLUS SRL.str. Valea Trandafirilor 24 "B", of. 2-7 MD-2001, ChisinauRepublic of Moldova of director **Iurchevici Valeriu** .,to carry out all necessary procedures on process of examination at state registration production of the PRINCIPAL in RSE with the REM "National Centre for Expertise of Drugs and Medical Products" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of MOLDOVA namely:

-to represent interests of the PRINCIPAL duringexamination at state registration(re-registration,making amendments) medical equipment;

-to submit all necessary registration materials (reg-istration file) on examination at state registrationmedical equipment;

-to conduct correspondence with competent bodiesand establishments;

-to receive the Registration Certificates (duplicate)on medical equipment, products of medical purposeand drugs.

-to sign all necessary documents (contracts, appli-cations, correspondence).

The present authorization letter is given for 3 (three) year or up to the moment of its response and can be sub-delegated.28.06.2026

Mia Med
MEDİKAL TEKSTİL İNŞ. TURZ. GIDA TİC. ve SAN. LTD. ŞTİ.
Şevket Sümer Mh. 5954 Sk. No:13/A
T. 0324 502 35 11 Akdeniz / MERSİN
LİMAN V.D. 621 097 6569

"ECHIPAMED-PLUS"
IDNO 1003600077677

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 üretttiğimizi 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

"TEHNIPAMED-PLUS" IDNO 1003600077677

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Ebulula Mardin Cad. Yıldırım Oğuz Gökçe Sokak
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Mia Med

CE

Mia Med
FOR A HEALTHIER FUTURE...

+90 324 502 35 11
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www.mia-medical.com
info@mia-medical.com
Şevket Sümer Mah. 5954 Sokak No :13A Akdeniz /MERSIN

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:

Electrıcal Hospıtal Bed : BED-1,BED-2,BED-3,BED-4,BED-5,BED-6,BED-13,BED-8,BED-14, MIA 06-S RED LINE
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
lnfusion 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 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/ Al (Graphs and Symbols Used on labels) EN 1401(lnformation 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/ Al: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

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

„ECHIPAMED-PLUS" CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA

444 1 279

Nr.	Numărul de catalog (referință)	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)	Modelul	Cod GMDN
1		Pat pentru examinare		MIA 3086	
2		Brancarda		STR-3	
3		Brancarda		STR-4	
4		Pat functional		MIA 06-S RED LINE	
5		Pat pediatric		BED-15	
6		Fotoliu ginecologic		MIA GT-01