

POWER OF ATTORNEY

The Company **ERMED TIP MEDİKAL TİCARET A.Ş** located in Türkiye (legal address: Kosekoy mah.Yılmaz sok no 15/1 41250 Kartepe Kocaeli) hereinafter called - «The Manufacturer», duly represented by the CEO, Mr. Eray Karatas; acting under and by virtue of the Articles of Association.

By this power of attorney authorizes:

The Company «**Comert-Magor**» S.R.L., Registration number: 1003600022518 located at str. Bucuriei 1, mun. Chisinau, MD-2004, Moldova, hereinafter called - «An authorized representative of the manufacturer».

- To represent the interests of The Manufacturer on the circulation of medical devices produced by **ERMED TIP MEDİKAL TİCARET A.Ş** ., on the territory of the Republic of Moldova.
- To register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.;
- To conduct negotiations;
- To sign the statements, applications, contracts and other necessary documents, including financial, with the purpose of state registration and conformity assessment of medical devices;
- To provide with technical, operational and other documentation and materials required for the state registration and conformity assessment of the medical device, to give clarifying explanation;
- To initiate changes to the registration certificate for medical devices, if it is necessary;
- To provide with other necessary information and documents for the state registration and conformity assessment of medical device;
- To make payments for the services;
- To perform other necessary actions related to the registration or conformity assessment of the medical device;
- To get the Registration certificate issued in the name of **ERMED TIP MEDİKAL TİCARET A.Ş**

This power of attorney is granted for **5 years**, with a right of substitution.

ERMED TIP MEDİKAL TİCARET A.Ş

Date :14.09.2023

ERMED TIP MEDİKAL TİCARET A.Ş.
Köseköy Mahallesi Yılmaz Sok. No:15/1
Kartepe / KOCAELİ Tel: 0262 223 44 86
Alemdar V.D. 3640490515
Mersis No: 0364049051500001

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, 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 dispozitivelor medicale:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
EASY411027	Bandaj elastic compresiv	EasyFlow	8 cm x 2M	Bandaj elastic	10284	Clasa I

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir

Semnătura _____

Data 17.09.2023

Către
 Agenția Medicamentului
 și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
 al dispozitivelor medicale

nr. 29 din 17.09.2023

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail veracojocar@gmail.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:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
EASY411027	Bandaj elastic compresiv	EasyFlow	8 cm x 2M	Bandaj elastic	10284	Clasa I

Se anexează următoarele acte:

- declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
- certificatul de management al calitatii pentru dispozitivele medicale ISO 13485:2016
- actul prin care producătorul își desemnează reprezentantul

Data **17.09.2023**

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	

EU DECLARATION OF CONFORMITY

MANUFACTURER: ERMED TIP MEDICAL TIC AŞ

ADDRESS: KÖSEKÖY MAHALLESİ YILMAZ SOKAK NO:15/1 KARTEPE/KOCAELİ

Tel: 0.262.2234480

Product name: ELASTIC BANDAGE

Brand: EASYFLOW

Model: Is stated in the appendix.

GMDN: 10284

Purpose of use : It is an elastic bandage wrapped around the bone joint that restricts the freedom movement in cases of malfunctions in the bone joint areas.

Basic UDI-DI: 86820760EASY037R6

Class: Class I-Other (non-sterile and without measuring function)

Directive: 2017/745 (Medical Device Regulations)

Conformity Assessment Rule: October 2017/745 (Medical Device Regulation) annex-IV declaration of conformity (annex II & III)

Standards applied: EN ISO 13485 :2016, TS EN ISO 14971: 2013. EN 1041 / A1:] 014, TS EN ISO 15223-i: 2016, DIN EN 6011994. EN 62366-1 / AC:2016: 2018, MEDDEV 2.12.1 REV.08. MEDDEV 2.7.1 REV.04. NBOG 2010-1

Certificate No: EASYFLOW-24082021-031

WITH THIS DOCUMENT, WE DECLARE THAT THE PRODUCTS MENTIONED ABOVE COMPLY WITH THE PROVISIONS OF THE MEDICAL DEVICE REGULATION 2017/745 ON MEDICAL DEVICES. ALL SUPPORTING DOCUMENTS ARE KEPT IN THE MANUFACTURER'S BUILDINGS. WE DECLARE THAT OUR PRODUCTS DO NOT CONTAIN HUMAN BLOOD, ANIMAL SKIN, OR PRODUCTS DERIVED FROM THESE PRODUCTS.

PLACE, DATE: Kocaeli, 24.08.2022

SIGNATURE:

ERAY KARATAŞ

Company Director

ERMED TIP MEDİKAL TİCARET A.Ş.
Köseköy Mahallesi Yılmaz Sok. No:15/1
Kartepe / KOCAELİ Tel: 0262 223 44 80
Alemdar V.D. 3640490515
Mersis No: 0364049051500001

APPENDIX - MODELS

PRODUCT NAME	SIZE
ELASTİC BANDAGE	5cm x 1mt
ELASTİC BANDAGE	5cm x 1.5mt
ELASTİC BANDAGE	5cm x 2mt
ELASTİC BANDAGE	5cm x 2.5mt
ELASTİC BANDAGE	5cm x 3mt
ELASTİC BANDAGE	5cm x 4mt
ELASTİC BANDAGE	5cm x 5mt
ELASTİC BANDAGE	6cm x 1mt
ELASTİC BANDAGE	6cm x 1.5mt
ELASTİC BANDAGE	6cm x 2mt
ELASTİC BANDAGE	6cm x 2.5mt
ELASTİC BANDAGE	6cm x 3mt
ELASTİC BANDAGE	6cm x 4mt
ELASTİC BANDAGE	6cm x 5mt
ELASTİC BANDAGE	8cm x 1mt
ELASTİC BANDAGE	8cm x 1.5mt
ELASTİC BANDAGE	8cm x 2mt
ELASTİC BANDAGE	8cm x 2.5mt
ELASTİC BANDAGE	8cm x 3mt
ELASTİC BANDAGE	8cm x 4mt
ELASTİC BANDAGE	8cm x 5mt
ELASTİC BANDAGE	10cm x 1mt
ELASTİC BANDAGE	10cm x 1.2mt

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ELASTİC BANDAGE	10cm x 1.3mt
ELASTİC BANDAGE	10cm x 1.5mt
ELASTİC BANDAGE	10cm x 2mt
ELASTİC BANDAGE	10cm x 2.5mt
ELASTİC BANDAGE	10cm x 2.7mt
ELASTİC BANDAGE	10cm x 3mt
ELASTİC BANDAGE	10cm x 4mt
ELASTİC BANDAGE	10cm x 4.5mt
ELASTİC BANDAGE	10cm x 5mt
ELASTİC BANDAGE	12cm x 1mt
ELASTİC BANDAGE	12cm x 1.2mt
ELASTİC BANDAGE	12cm x 1.3mt
ELASTİC BANDAGE	12cm x 1.5mt
ELASTİC BANDAGE	12cm x 2mt
ELASTİC BANDAGE	12cm x 2.5mt
ELASTİC BANDAGE	12cm x 2.7mt
ELASTİC BANDAGE	12cm x 3mt
ELASTİC BANDAGE	12cm x 4mt
ELASTİC BANDAGE	12cm x 5mt
ELASTİC BANDAGE	12cm x 7mt
ELASTİC BANDAGE	15cm x 1mt
ELASTİC BANDAGE	15cm x 1.2mt
ELASTİC BANDAGE	15cm x 1.3mt
ELASTİC BANDAGE	15cm x 1.5mt
ELASTİC BANDAGE	15cm x 2mt
ELASTİC BANDAGE	15cm x 2.5mt
ELASTİC BANDAGE	15cm x 2.7mt

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ELASTİK BANDA	15cm x 3mt
ELASTİK BANDA ELASTİK BANDA	15cm x 4mt
ELASTİK BANDA	15cm x 4.5mt
ELASTİK BANDA	15cm x 5mt
ELASTİK BANDA	20cm x 1mt
ELASTİK BANDA	20cm x 1.2mt
ELASTİK BANDA	20cm x 1.3mt
ELASTİK BANDA	20cm x 1.5mt
ELASTİK BANDA	20cm x 2mt
ELASTİK BANDA	20cm x 2.5mt
ELASTİK BANDA	20cm x 2.7mt
ELASTİK BANDA	20cm x 3mt
ELASTİK BANDA	20cm x 4mt
ELASTİK BANDA	20cm x 4.5mt
ELASTİK BANDA	20cm x 5mt

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 Kartepe / KOCAELİ Tel: 0262 223 44 80
 Alemdar V.D. 3640490515
 Mersis No: 0364049051500001



Certificate of Registration

This is to certify that
Quality Management System
of

ERMED TIP MEDİKAL TİCARET ANONİM ŞİRKETİ

KÖSEKÖY MAH. YILMAZ SOK. NO:15/1
KARTEPE - KOCAELİ / TÜRKİYE

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to;

PRODUCTION, IMPORT, EXPORT, STORAGE AND SALES OF ALL STERILE AND NON-STERILE MEDICAL CONSUMABLES, GAUZE DRESSING AND COMPRESS, ORTHOPEDIC CAST AND COTTON, SPLINT, BANDAGES, ANTIEMBOLI STOCKING, DIAPER AND UNDERPAD, ABSORBENT PADS, MEDICAL COTTON, VAGINAL SPECULUM, WOODEN TONGUE DEPRESSOR, ENEMA SET, SHARP CONTAINERS, 3 BALLS EXERCISER, GOWN, SHOE COVER, HAIR COVER, SURGICAL FACE MASK, ADHESIVE TAPES, SKIN CLEANING WIPES, GLOVES, SYRINGES AND NEEDLES, STERILIZATION ROLLS, BREATHING SYSTEM CIRCUITS, FILTERS AND TUBES, NEBUL AND OXYGEN MASK, ANESTHESIA MASKS, DRAINS AND BAGS, CATHETERS, CANNULAS, URINE BAGS, PRESSURE TRANSDUCER SET, LANCET, ADHESIVE AND HEMOSTATS, SURGICAL MESHES, WOUND AND BURN CARE CONSUMABLES, MEDICAL USE BAGS, ELECTRODES, ELECTROSURGICAL PENCIL AND PLATE, SKIN STAPLER, SMEAR BRUSH, CLAMPS, IV CANNULAS, BLOOD BAG AND FILTER AND ALL OTHER MEDICAL CONSUMABLES, PROTECTIVE COVERALLS AND PERSONAL PROTECTIVE EQUIPMENTS

QMS-1460.235
Certificate No.

Jan. 25, 2023
Date of this Certificate

Jan. 24, 2024
Certification Expiry Date

Dec. 22, 2022
Date of Audit

Jan. 25, 2023
Date of Registration


Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

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Certificate of Registration

Bu Sertifika,

Kalite Yönetim Sistemi

gereksinimlerine uygun olarak

ERMED TIP MEDİKAL TİCARET ANONİM ŞİRKETİ

KÖSEKÖY MAH. YILMAZ SOK. NO:15/1

KARTEPE - KOCAELİ / TÜRKİYE

yukarıda adı geçen kuruluşa,

ISO 9001:2015

Şartlarına uygun bir Kalite Yönetim sistemine aşağıda
belirtilen kapsam dahilinde sahip olduğunu onaylar;

STERİL VE NONSTERİL TÜM TIBBİ SARF MALZEMELER, GAZLI BEZ VE KOMPRES, ORTOPEDİK ALÇI VE PAMUĞU, ATEL, BANDAHLAR, ANTIEMBOLİ ÇORABI, HASTA BEZİ VE YATAK KORUYUCU, EMİCİ PEDLER, TIBBİ PAMUK, VAJİNAL SPEKULUM, ABESLANG, LAVMAN SETİ, TIBBİ ATIK KOVALARI, TRİFLO, ÖNLÜK, GALOŞ, BONE, CERRAHİ MASKE, YAPIŞKANLI FLASTERLER, CİLT TEMİZLEME MENDİLLERİ, EL DİVENLER, ENJEKTÖRLER VE İĞNE UÇLARI, STERİLİZASYON RULOLARI, SOLUNUM GRUBU DEVRELER, FİLTRELER VE TÜPLER, NEBÜL VE OKSİJEN MASKESİ, ANESTEZİ MASKELERİ, DRENLER VE TORBALAR, KATETERLER, KANÜLLER, İDRAR TORBALARI, BASINÇ İZLEME SETLERİ, LANSET, YAPIŞTIRICI VE KANAMA DURDURUCULAR, CERRAHİ YAMALAR, YARA VE YANIK BAKIM SARFLARI, MEDİKAL KULLANIMLI TORBALAR, ELEKTRODLAR, KOTER KALEMİ VE PLAĞI, CİLT STAPLERİ, SMEAR FIRÇASI, KLEMLER, BRANÜLLER, KAN TORBASİ VE FİLTRESİ VE DİĞER TIBBİ MALZEME SARFLARIN ,KORUYUCU TULUM VE KİŞİSEL KORUYUCU EKİPMANLARIN ÜRETİMİ, İTHALATI, İHRACATI, DEPOLAMASI VE SATIŞI

QMS-1460.235
Sertifika No.

Ara. 22, 2022
Denetim Tarihi

Oca. 25, 2023
Sertifika Tarihi

Oca. 25, 2023
Kayıt Tarihi

Oca. 24, 2024
Sertifika Geçerlilik Tarihi


Genel Müdür



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
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Certificate of Registration

This is to certify that

**Quality Management System
for Medical Devices**

of

ERMED TIP MEDİKAL TİCARET ANONİM ŞİRKETİ

KÖSEKÖY MAH. YILMAZ SOK. NO:15/1
KARTEPE - KOCAELİ / TÜRKİYE

complies with requirements of

ISO 13485:2016

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Certificate of Registration

Bu Sertifika,
Medikal Cihazlar için
Kalite Yönetim Sistemi
gereksinimlerine uygun olarak

ERMED TIP MEDİKAL TİCARET ANONİM ŞİRKETİ

KÖSEKÖY MAH. YILMAZ SOK. NO:15/1
KARTEPE - KOCAELİ / TÜRKİYE

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MQMS-1460.236
Sertifika No.

Oca. 25, 2023
Sertifika Tarihi

Oca. 24, 2024
Sertifika Geçerlilik Tarihi

Ara. 23, 2022
Denetim Tarihi

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