

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. din

Solicitantul Ericon S.R.L., cu sediul Durlesti, V. Lupu 6, tel./fax: +373 22 52 01 08, +373 6000 6226, e-mail bunic.cornel@gmail.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:

- Turmed TM-A 1009

Se anexează următoarele acte:

- a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
- b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;
- c) actul prin care producătorul își desemnează reprezentantul.

Data _____

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: Ericon S.R.L., cu sediul or. Durlști, str. Vasile Lupu, nr. 6 , 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:

- Turmed TM-A 1009

Sunt autentice și corespund realității.

Corneliu Bunic

Semnătura _____

Data _____

REGISTERED COMMERCIAL TITLE AND ADDRESS OF THE MANUFACTURER:

TUR-MED HASTANE MALZEMELERİ SAN VE TİC. LTD. ŞTİ.

-SEYHAN MAHALLESİ 722/1 SOKAK NO: 30 BUCA- İZMİR

-İTOB OSB MAHALLESİ 10035.SOKAK NO: 1 MENDERES-İZMİR

VIII. RISK CLASS OF THE DEVICE ACCORDING TO THE RULES SET FORTH IN THE ATTACHMENT;
CLASS 1

WE ARE THE MANUFACTURER OF THE DEVICES LISTED BELOW AND THAT THE DEVICES ARE
COMPLIANT WITH THE MEDICAL DEVICE REGULATION (EU) 2017/745 (MDR) AND MEET ALL
RELEVANT REQUIREMENTS WITHIN THE MDR.

METHOD OF ASSESSMENT OF CONFORMITY: ANNEX-IV DECLARATION OF CONFORMITY (ANNEX
II & APPENDIX III)

CHAPTER III OF THE PRODUCTS MEDICAL DEVICE REGULATION APPENDIX VIII 4.1- RULE 1 /
CLASS:1 ALL NON-INVASIVE DEVICES ARE CLASSIFIED AS CLASS I.

COMMON SPECIFICATIONS: EN ISO 13485:2016, EN ISO 14971: 2019, EN ISO 15223-1:2016, EN ISO
9001:2015, EN ISO 14001:2015, EN ISO 45001:2018.

THIS DECLARATION OF CONFORMITY IS CREATED SOLELY UNDER THE MANUFACTURER'S
RESPONSIBILITY.

PLACE AND DATE OF ISSUING THE DECLARATION,
İZMİR , 11.07.2023

Mehmet Onur Yenil
General Manager

turmed Hast. Malz. San.
ve Tic. Ltd. Şti.
Merkezi: Seyhan Mahallesi 722/1 Sokak No: 30 Buca/İZMİR
İTOB OSB Mahallesi 10035 Sokak No: 1 Menderes/İZMİR
Tic. Sic. No: 272203 294 13 15 254 76 03
Fon: 0312 254 76 03
Fax: 0312 254 76 03

TUR-MED HASTANE MALZEMELERİ SAN. VE TİC. LTD. ŞTİ.
Center Office: SEYHAN MAHALLESİ 722/1 SOKAK NO:30 BUCA- İZMİR
Factory: İTOB OSB MAHALLESİ 10035.SOKAK NO:1 MENDERES-İZMİR

PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943380017	869894338GEN01TF	38458	V080603	TM-A-1001	EXAMINATION TABLE (FOLDING)
8698943380062	869894338GEN01TF	38458	V080603	TM-A-1002	EXAMINATION TABLE (FIXED)
8698943380079	869894338GEN01TF	38458	V080603	TM-A-1003	EXAMINATION TABLE (WOODEN)
8698943380048	869894338GEN01TF	38458	V080603	TM-A-1004	EXAMINATION TABLE (WOODEN)
8698943380055	869894338ORT0123	38458	V080603	TM-A-1005	EXAMINATION TABLE (WOODEN)
8698943383773	8698943383MSJUF	32266	V080603	TM-A-1006	MASSAGE TABLE
8698943383780	8698943383MSJUF	32266	V080603	TM-A-1007	MASSAGE TABLE (BAG TYPE)
8698943380093	869894338ORT0123	10789	V080202	TM-A-1009	BLOOD DONOR CHAIR
8698943380109	869894338GEN01TF	10789	V080202	TM-A-1010	BLOOD DONOR CHAIR
8698943380116	869894338GEN01TF	36065	V080603	TM-A-1011	GYNEACOLOGICAL EXAMINATION TABLE
8698943380130	869894338GEN01TF	13960	V080603	TM-A-1013	GYNEACOLOGICAL EXAMINATION TABLE
8698943381595	869894338MAS01VE	36065	V08020199	TM-A 1020	GYNEACOLOGICAL EXAMINATION CHAIR (TWO MOTOR)
8698943381601	869894338MAS01VE	36065	V08020199	TM-A 1021	GYNEACOLOGICAL EXAMINATION CHAIR (THREE MOTOR)
8698943381625	869894338MAS01VE	10789	V08020199	TM-A 1022	BLOOD DONOR CHAIR (TWO MOTOR)
8698943381632	869894338MAS01VE	10789	V08020199	TM-A 1023	BLOOD DONOR CHAIR (THREE MOTOR)
8698943381250	869894338MAS01VE	31362	V080603	TM-A 1025	EXAMINATION TABLE (SINGLE MOTOR)
8698943381243	869894338MAS01VE	31362	V080603	TM-A 1026	EXAMINATION TABLE (TWO MOTOR)
8698943381618	869894338MAS01VE	36065	V080603	TM-A-1027	GYNEACOLOGY AND DELIVERY TABLE



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PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943387405	869894338ORT0123	36801	V0899	TM-B-2003	MAYO TABLE
8698943383896	869894338TDV4F	40542	V0899	TM-B-2010	DRESSING TROLLEY
8698943383926	869894338TDV4F	40542	V0899	TM-B-2014	DRESSING TROLLEY
8698943383933	869894338TDV4F	40542	V0899	TM-B-2015	DRESSING TROLLEY
8698943383995	869894338TDV4F	40542	V0899	TM-B-2021	EMERGENCY AND MEDICINE TROLLEY (28 COMP.)
8698943384022	869894338TDV4F	40542	V0899	TM-B-2024	EMERGENCY AND MEDICINE TROLLEY (8 COMP.)
8698943384046	869894338TDV4F	40542	V0899	TM-B-2026	EMERGENCY AND MEDICINE TROLLEY (8 COMP.)
8698943384060	869894338TDV4F	40542	V0899	TM-B-2028	EMERGENCY AND MEDICINE TROLLEY (20 COMP.)
8698943384084	869894338TDV4F	40542	V0899	TM-B-2030	EMERGENCY AND MEDICINE TROLLEY (30 COMP.)
8698943380383	869894338SED01VZ	13818	V08050101	TM-C-3001	STRETCHER (FOLDING)
8698943380390	869894338SED01VZ	35892	V08050101	TM-C-3002	STRETCHER (WITH UPPER PLATFORM)
8698943381274	869894338SED01VZ	13818	V08050101	TM-C-3003	STRETCHER
8698943380444	869894338SED01VZ	35843	V08050101	TM-C-3007	STRETCHER
8698943380475	869894338SED01VZ	35843	V08050103	TM-C-3010	AMBULANCE STRETCHER
8698943381281	869894338SED01VZ	35892	V08050101	TM-C-3017	STRETCHER (HYDRAULIC)
8698943383766	869894338SED01VZ	35892	V08050103	TM-C-3033	EMERGENCY STRETCHER



PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943380505	869894338KA01SW	34873	V080603	TM-D-4001	PATIENT BED
8698943380512	869894338KA01SW	34873	V080603	TM-D-4002	PATIENT BED (SINGLE SETTING)
8698943380529	869894338KA01SW	34873	V080603	TM-D-4003	PATIENT BED (TWO SETTING)
8698943380628	869894338KA01SW	34873	V080603	TM-D-4013	PATIENT BED (SINGLE SETTING)
8698943380666	869894338KA01SW	34873	V080603	TM-D-4017	PATIENT BED (TWO SETTING)
8698943380697	869894338KA01SW	34873	V080603	TM-D-4020	PATIENT BED (TWO SETTING WITH BEDPAN)
8698943389829	869894338KA01SW	34873	V080603	TM-D-4027	PATIENT BED (THREE SETTING)
8698943380833	869894338MAS01VE	34873	V08060101	TM-D 4034	PATIENT BED (DUAL MOTOR)
8698943380857	869894338ORT0123	14105	Z12130202	TM-D-4036	ORTHOPEDIC TRACTION FRAME
8698943381687	869894338MAS01VE	34870	V08060102	TM-D 4053	INTENSIVE CARE UNIT BED (FOUR MOTOR)
8698943381663	869894338KA01SW	34870	V08060101	TM-D-4055	PATIENT BED (THREE MOTOR)
8698943381335	869894338MAS01VE	34870	V08060101	TM-D 4056	PATIENT BED (FOUR MOTOR)
8698943381366	869894338MAS01VE	34870	V08060101	TM-D 4058	PATIENT BED (THREE MOTOR)



PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943381373	869894338KA01SW	34870	V08060101	TM-D-4059	PATIENT BED (FOUR MOTOR)
8698943381342	869894338MAS01VE	34870	V08060101	TM-D 4060	PATIENT BED (DUAL MOTOR)
8698943381359	869894338MAS01VE	34870	V08060101	TM-D 4062	PATIENT BED (DUAL MOTOR)
8698943381380	869894338MAS01VE	13960	V08060101	TM-D 4065	DELIVERY BED (FOUR MOTOR)
8698943381397	869894338MAS01VE	13960	V08060101	TM-D 4066	DELIVERY BED (THREE MOTOR)
8698943380642	869894338KA01SW	34873	V080602	TM-D-4067	PATIENT BED (SINGLE SETTING)
8698943387733	869894338KA01SW	35183	V080399	TM-D 4069	CNC MATTRESS
8698943381311	869894338KA01SW	34870	V080602	TM-D-4070	PATIENT BED (THREE SETTING)
8698943380680	869894338KA01SW	34873	V080602	TM-D-4071	PATIENT BED (THREE SETTING)
8698943387740	869894338KA01SW	34871	V080602	TM-D-4073	PATIENT BED (SINGLE SETTING)
8698943387757	869894338KA01SW	34871	V080602	TM-D-4074	PATIENT BED (TWO SETTING)
8698943388396	869894338MAS01VE	30032	V080601	TM-D-4077	PATIENT BED (DUAL MOTOR)
8698943384121	869894338KA01SW	35183	V08030102	TM-D-4078	ANTI DECUBITUS MATTRESS
8698943384138	869894338KA01SW	35183	V08030102	TM-D-4079	ANTI DECUBITUS MATTRESS
8698943388402	869894338MAS01VE	30032	V08060102	TM-D 4080	INTENSIVE CARE UNIT BED (FIVE MOTOR)



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Factory: İTOB OSB MAHALLESİ 10035.SOKAK NO:1 MENDERES-İZMİR

PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943381120	869894338GEN01TF	36488	Z11069005	TM-F-6003	NEGATOSCOPE (SINGLE)
8698943381137	869894338ORT0123	36488	Z11069005	TM-F-6004	NEGATOSCOPE (DOUBLE)
8698943381144	869894338ORT0123	36488	Z11069005	TM-F-6005	NEGATOSCOPE (TRIPLE)
8698943387955	869894338ORT0123	16800	V0899	TM-F-6007	EYE SCALE
8698943381175	869894338ORT0123	36069	V0880	TM-F-6008	IV STAND
8698943381212	869894338ORT0123	36069	V0880	TM-F-6012	IV STAND
8698943387962	869894338ORT0123	12276	Z129004	TM-F-6013	EXAMINATION LAMP



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Factory: İTOB OSB MAHALLESİ 10035.SOKAK NO:1 MENDERES-İZMİR

PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943389027	869894338KA01SW	37010	V080602	TM-K-2203	PEDIATRIC BED (SINGLE SETTING)
8698943389065	869894338ORT0123	38140	V0809	TM-K-2207	INFANT COT
8698943389072	869894338KA01SW	37008	V08060199	TM-K-2208	INFANT BED
8698943381458	869894338ORT0123	38140	V0809	TM-K-2210	INFANT COT
8698943389089	869894338ORT0123	37010	V080602	TM-K-2211	PEDIATRIC MATTRESS
8698943381441	869894338MAS01VE	38140	V08060107	TM-K-2213	PEDIATRIC PATIENT BED (SINGLE MOTOR)
8698943381403	869894338SED01VZ	35892	V08050101	TM-K-2215	PEDIATRIC STRETCHER
8698943381489	869894338GEN01TF	38458	V080603	TM-K-2216	PEDIATRIC EXAMINATION TABLE
8698943381472	869894338GEN01TF	38458	V080603	TM-K-2217	PEDIATRIC EXAMINATION TABLE (WOODEN)
8698943381434	869894338MAS01VE	38140	V08060107	TM-K-2219	PEDIATRIC PATIENT BED (TWO MOTOR)

İZMİR, 11.07.2023
Mehmet Onur Yenil
General Manager

turmed Hast. Malz. San.
ve Tic. Ltd. Şti.
Menderes Mahallesi 722/1 Sokak No:30 Buca/İZMİR
Tic. Sic. No: 270935 Şişli No:1 Menderes/İZMİR
İTOB 2. Kat: 11.03.2018 25.13.15 254 76 33
Fab. No: 10035 10035 10035 10035
Gazetesi: TD: 005 1302

TUR-MED HASTANE MALZEMELERİ SAN. VE TİC. LTD. ŞTİ.
Center Office: SEYHAN MAHALLESİ 722/1 SOKAK NO:30 BUCA- İZMİR
Factory: İTOB OSB MAHALLESİ 10035.SOKAK NO:1 MENDERES-İZMİR

Tarih:...../...../20.....

We, TUR-MED HASTANE MALZEMELERİ SAN.VE TİC. LTD.ŞTİ.

based in 10035 SOKAK NO:1 İTOB MENDERES-İZMİR TURKEY

assign ERICON SRL, based in 6,Vasile Lupu str. Durleşti. Republic of Moldova

as **authorized representative** in correspondence with the conditions of directive 2017/745, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Place: İZMİR

Date: 02.11.2021

Signed:

turmed San. Tic. Ltd. Şti.

Merkez Fab. 722/1 Sokak No:30-32 Buca/İZMİR
İTOB Org.San. Bölge 10035 Sokak No:1 Menderes
Fab. Tel&Fax: 0 232 441 13 16 - 254 76 33
Kemeraltı Show Room : 0 232 441 70 18
İzmir İthalat V.D. : 867 005 1302

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
TM-A 1009	Fotoliu pentru colectarea sângei	Blood donor chair	TM-A 1009	Fotoliu pentru colectarea sângei	10789