

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____

Solicitantul Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,
(adresa)

tel./fax: (022) 44 50 65, e-mail farma@tetis.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:

- Dispozitive medicale conform listei:

Nr.	Modelul	Nr de catalog	Denumire
1	PATIENT BED (FOUR MOTOR)	TM-D 4056	PAT FUNCȚIONAL DE SPITAL
2	ergoselect 4	191001	CICLOERGOMETRU

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 _____

Tablelul 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 Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,

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:

- Dispozitive medicale conform listei:

Nr.	Modelul	Nr de catalog	Denumire
1	PATIENT BED (FOUR MOTOR)	TM-D 4056	PAT FUNCȚIONAL DE SPITAL
2	ergoselect 4	191001	CICLOERGOMETRU

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Data

Semnătura _____



Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						labtech			
DM000221013	ELECTROCARDIOGRAF - STRES TEST	CARDIOSPY®	EC-12R/S		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221014	ELECTROCARDIOGRAF - STRES TEST	CARDIOSPY®	EC-3RT		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221016	ELECTROCARDIOGRAF - STRES TEST	CARDIOSPY®	EC-12LT		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221011	ELECTROCARDIOGRAF - STRES TEST	CARDIOSPY®	EC-12RM		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221002	ELECTROCARDIOGRAF	CARDIOSPY®	EC-3H/ABP, HOLTER		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000220999	ELECTROCARDIOGRAF	CARDIOSPY®	EC-3H, HOLTER		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221001	ELECTROCARDIOGRAF	CARDIOSPY®	EC-ABP, HOLTER		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221012	ELECTROCARDIOGRAF - STRES TEST	CARDIOSPY®	EC-12S		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000220998	ELECTROCARDIOGRAF	CARDIOSPY®	EC-2H, HOLTER		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019
DM000221000	ELECTROCARDIOGRAF	CARDIOSPY®	EC-12H, HOLTER		Ungaria	LABTECH LTD.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000167	16-07-2019

EG-KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY



Wir / We

ergoline GmbH
Lindenstr. 5
72475 Bitz (Germany)

erklären in alleiniger Verantwortung,
dass das Medizinprodukt /
declare on our own responsibility that the
medical device

Ergometer / ergometer

Serie / series

Ergoselect 4 mit Artikel-Nr. 191001 / ergoselect 4 with article
no.: 191001
Ergoselect 5 mit Artikel-Nr. 191002 / ergoselect 5 with article
no.: 191002

Erweiterbar um die Optionen /
expandable by options

Bestell-Nr./ order no.:	Abkürzung en / abbre.	Bezeichnung / description
191806	B	Automatische Blutdruckmessung / automatic blood pressure measurement
191807	S	Automatische Messung Sauerstoffsättigung / automatic SpO2 measurement
191801	P	Bedieneinheit Ergometrie (Typ "P") / control unit ergometry (type „P“)
191802	T	Farb-/Touch Bedieneinheit (Typ "T") / color touch control unit (type „T“)
191810	Y	Bluetooth-Schnittstelle / bluetooth interface
191811	W	WLAN-Schnittstelle / WiFi interface

Mit Zubehör / with accessories

Bestell-Nr./ order no.:	Abkürzung en / abbr.	Bezeichnung / description
705944	Q	Komfort-Pedalschlaufen / comfort pedal straps
191803	G	Sattelhöhen-Verstellung mit Gasdruckfeder / saddle height adjustment with gas spring
191804	E	Sattelhöhen-Verstellung mit Motor / horizontal saddle adjustment
191805	L	Lenkerhöhen-Verstellung elektrisch / handlebar height adjustment with motor
191808	D	HF Empfang ergoline digital / cardio set „ergoline digital“
191809	X	Kardio-Set „Polar“ / cardio set „Polar“

mit den Anforderungen der Richtlinie
übereinstimmt/
is in conformity with the Directive

93/42/EWG: Anhang II (ohne 4)

93/42/EEC: annex II (excluding 4)

Zertifikatsnummer / Certificate Number
Gültigkeit / Validity

G1 044463 0022 Rev. 01
26.05.2024

UMDNS-Code / UMDNS-Code

10383

Benannte Stelle / Notified Body

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 München
Germany

Konformitätsbewertungsverfahren /
Conformity assessment procedure

Anhang II (ohne 4)
annex IX / rule 10

Klasse / Class

Ila

Klassifizierung nach /
Classification according to

Anhang IX / Regel 10
annex IX / rule 10

Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 15.10.2019

Ort/City:

Bitz den, 2020-02-24



Axel Bodmer
Qualitätsmanagement / Quality Manager

ergoline^{GmbH}
Lindenstraße 5 • D-72475 Bitz
Tel.: +49(0)7431 • 9894-0

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
-ITOB 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 , 03.07.2023

Mehmet Onur Yenil
General Manager


turmed Hast. Malz. San.
ve Tic. Ltd. Şti.
Menderes San. Bölgesi 722/191 No:30-32 Buca/İZMİR
K. Tic. Sic. No: 270935 Şişli Menderes/İZMİR
İTOB OSB San. Bölgesi 10035 No:1 Menderes/İZMİR
Tic. Sic. No: 270935 13 16 254 76 00
Geniştirme No: 967 005 1302

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



PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943387405	869894338ORT0123	36801	V08	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	V0803	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	V080301	TM-D-4078	ANTI DECUBITUS MATTRESS
8698943384138	869894338KA01SW	35183	V080301	TM-D-4079	ANTI DECUBITUS MATTRESS
8698943388402	869894338MAS01VE	30032	V08060102	TM-D 4080	INTENSIVE CARE UNIT BED (FIVE MOTOR)



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



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, 03.07.2023
Mehmet Onur Yenil
General Manager

turmed Hast. Malz. San.
ve Tic. Ltd. Şti.
Merkezi: Seyhan Mahallesi 722/1 Sokak No:30-32 Buca/İZMİR
Tic. Sic. No: 270954 Şişli No:1 Menderes/İZMİR
İTOB 2. Etap II. Etap Mahallesi Sokak No:1 Menderes/İZMİR
Fab. Sic. No: 270954 13 15 254 76 33
Gazetesi No: 867 005 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



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 044463 0022 Rev. 01

Manufacturer: **Ergoline GmbH**
 Lindenstr. 5
 72475 Bitz
 GERMANY

Facility(ies): Ergoline GmbH
 Lindenstr. 5, 72475 Bitz, GERMANY

Product Category(ies): **Ergometer, Blood Pressure Measuring
 Instruments, SpO2 Devices and Medical
 Software for Rehabilitation and Training**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168681

Valid from: 2020-02-17

Valid until: 2024-05-26

Date, 2020-02-17

Christoph Dicks
 Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT