

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: „Neotec” SRL, cu sediul în mun.Chisinau, str.Zaikin, 37,

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:

1. Pat multifunctional pentru adulti T-8060

Sunt autentice și corespund realității.

Botnaru Andrei-Director

Semnătura _____ Data _____

Digitally signed by Botnaru Andrei
Date: 2023.09.29 12:04:22 EEST
Reason: MoldSign Signature
Location: Moldova



Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 02.10.2023

Solicitantul „Neotec” SRL, cu sediul mun.Chisinau, str.Zaikin, 37, tel./fax: 022 852250/ 022 852252, e-mail office@neotec.md, agb@neotec.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:

1. Pat multifunctional pentru adulti T-8060

Se anexează următoarele acte:

1. Lista dispozitivelor medicale solicitate spre notificare
2. Actul prin care producătorul își desemnează reprezentantul.
3. Declarație pe proprie răspundere
4. EC Declaration Of Conformity

Data 02.10.2023

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	



T-HEALTH

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Date: 2023.09.29 11:51:04 EEST
Reason: MoldSign Signature
Location: Moldova



EC DECLARATION OF CONFORMITY AVRUPA UYGUNLUK BEYANI



Date of issue / Yayınlanma Tarihi: 26.06.2023

Declaration of Conformity Issued by / Uygunluk Belgesini Yayınlayan:

Commercial Name of
the

Company / Firma Adı

GCP Number

GLN Number

Basic UDI-DI

Address / Adres

Telephone / Telefon

E-mail / E-posta

Brand / Marka

T HEALTH MEDİKAL İC VE DİS TİC. LTD. STİ.

868425262885

8684252628858

868425262885TDW

**Industrial Zone 1, Str. Nr: 66059, Bld. Nr: 30, Sehitkamil – Gaziantep /
TÜRKİYE**

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T-HEALTH

- T 8070 – 4 Motor ICU Bed / Columnar Motors
- T 8060 – 4 Motor ICU Bed
- T 8050 – 4 Motor ICU Bed
- T 8030 – 3 Motor ICU Bed
- T 8020 – 2 Motor ICU & Patient Bed
- T 8021 – 2 Motor ICU & Patient Bed / Collapsible Metallic Side-Rails
- T 8022 – Dual Motor ICU & Patient Bed / Collapsible Metallic Side-Rails
- T 8023 – 3 Motor Electronic Patient&Home Care Bed
- T 8024 – Electronic Patient&Home Care
- T 8025 – Electronic Hospital Bed
- T 1190 – Manual Hospital Bed
- T 1180 – Manual Hospital Bed
- T 1170 – Hydraulic Hospital Bed
- T 1160 – 3 Crank Manual Patient Bed
- T 1150 – Manual Hospital Bed
- T 1140 – Manual Hospital Bed with Trendelenburg&Reverse Trendelenburg Adjustments
- T 1130 – 2 Crank Manual Patient Bed
- T 1120 – 1 Crank Manual Patient Bed with Trendelenburg Movement
- T 1110 – 1 Crank Manual Patient & Ward Bed
- T 1100 – Flat Hospital Bed

Products / Ürünler

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- TMS 01 – Foam Mattress with Zippered Polyurethane Cover
- TMS 02 – Foam Mattress with Zippered Polyurethane Cover
- TMS 02_Pediatric – Pediatric Foam Mattress with Zippered Polyurethane Cover
- TMS 03 – Foam Mattress with Zippered Synthetic Cover
- TMS 04 – Foam Mattress with Cover
- TMS 05 – Foam Mattress with Cover
- TMV 01 – Viscoelastic Mattress with Zippered Polyurethane Cover
- TMV 02 – Viscoelastic Mattress with Cover
- TMV 03 – Viscoelastic Mattress with Cover
- TMV 04 – Viscoelastic Mattress with Cover
- BSC 2710 – HPL Bedside Cabinet with Tilting Over Bed Table
- BSC 2710_M – Metallic Bedside Cabinet with Tilting Over Bed Table
- BSC 2720 – HPL Bedside Cabinet
- BSC 2722 – Wooden Bedside Cabinet with Tilting HPL Over Bed Table
- BSC 2725 – Wooden Bedside Cabinet with Over Bed Table
- BSC 2730 – ABS Bedside Cabinet
- BSC 2740 – Metallic Bedside Cabinet with Over Bed Table
- BSC 2750 – Bedside Cabinet with ABS Cover
- BSC 2760 – Metallic Bedside Cabinet
- BSC 2770 – Wooden Bedside Cabinet
- BSC 2780 – Wooden Bedside Cabinet with ABS Top Cover
- BSC 2790 – Bedside Cabinet
- OBT 2710 – HPL Tilting Over Bed Table
- OBT 2720 – Height Adjustable Wooden Over Bed Table
- OBT 2730 – Height Adjustable ABS Over Bed Table
- OBT 2740 – Height Adjustable Wooden Over Bed Table
- OBT 2750 – HPL Over Bed Table
- OBT 2760 – Over Bed Table
- OBT 2770 – Wooden Food Table
- OBT 2780 – Over Bed Table
- OBT 2790 – Over Bed Table
- TA-3010 – Wooden Dresser Cupboard / Single
- TA-3020 – Wooden Dresser Cupboard / Double
- TR-3000 – Companion Chair
- T-Xpress Pioneer – Functional Hydraulic Emergency Stretcher
- T-Xpress – Functional Hydraulic Emergency Stretcher
- T-Xpress Basic – Basic Emergency Stretcher
- T-Xpress Hydro – Functional Emergency Stretcher



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T-HEALTH

- T-Ransfer – Operation Theatre Transfer Stretcher
- T-Couch – Patient Transfer Chair
- T-Couch 01 – Blood Drawing Chair
- T-Couch 02 – Patient Transfer Chair
- T-Couch 03 – Patient Transfer Chair
- T-Couch 04 – Patient Transfer Chair
- T-Couch 05 – Patient Transfer Chair
- T-Couch 06 – Patient Transfer Chair
- T-Couch 07 – Patient Transfer Chair
- T-Couch 08 – Manual Blood Drawing Chair
- T-Couch 09 – Patient Transfer Chair
- T-Swift AL – Stackable Patient Transfer Chair/Aluminium Structure
- T-Swift SS – Stackable Patient Transfer Chair/Stainless Steel Structure
- T-Swift EP – Stackable Patient Transfer Chair/Epoxy Painted Structure
- T 2800 / Manual Gynecology Examination Chair
- T 2810 / Hydraulic Delivery Bed
- T 2820 / 3 Motor Electronic Gynecology Examination Chair
- T 2840 / 4 Motor Electronic Delivery Bed
- T 2850 – 3 Motor Electronic Delivery Bed
- T 2860 – 3 Motor Electronic Gynecology Examination Chair
- T 2870 / Delivery-Gynecology Bed
- T 2880 / Delivery-Gynecology Bed
- T 2890 / Delivery-Gynecology Bed
- T 3300 / Baby Cote
- T 3310 / Baby Cote
- T 3320 / Baby Cote
- T 3327 / Dual Motor Electronic Pediatric Bed
- T 3330 / 3 Motor Electronic Pediatric Bed
- T 3340 / 4 Motor Electronic Pediatric Bed
- T 3350 / 2 Motor Electronic Pediatric Bassinet
- T 3360 / Pediatric Bed
- T 3370 / Pediatric Bed
- T 3380 – Hydraulic Pediatric Bed
- T 3390 / Pediatric Bed
- TE 100 – Electronic Functional Patient Chair
- TE 200 – Electronic Functional Patient Chair
- TE 300 – Electronic Functional Patient Chair
- TE 400 – Electronic Functional Patient Chair

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T-HEALTH

- TE 500_ENT – Electronic Ear Nose Throat (E.N.T.) Chair
- TE 600 – 4 Motor Electronic Blood Transfusion Chair
- TE 700 – 2 Motor Electronic Blood Transfusion Chair
- TE 800 – 4 Motor Electronic Dialysis & Chemotherapy Chair
- TE 900 – Electronic Functional Patient Chair
- T-Rolley Emergency – Functional Emergency Trolley
- T-Rolley Anesthesia – Functional Anesthesia Trolley
- T-Rolley Dressing – Functional Dressing Trolley
- T-Rolley Medication – Functional Medication Trolley
- T-Rolley Treatment – Functional Treatment Trolley
- TH 6510 – Metallic Medication Cart
- TH 6511 – Metallic Medication Cart
- TH 7510 – Metallic Dressing Cart
- TS 7510 – Stainless Steel Dressing Trolley
- TS 7511 – Stainless Steel Dressing Trolley with Drawers
- TS 7520 – Stainless Steel Anesthesia Trolley
- TS 7530 – Stainless Steel Medication Trolley
- TS 6007 – Stainless Steel Examination Table / Fixed Legs
- TS 6011 – Stainless Steel Examination Table / Foldable Legs
- TS 6210 – Stainless Steel Bench
- TS 6314 – Stainless Steel Foldable Patient Screen
- TS 6315 – Stainless Steel IV Pole with Castors
- TS 7010 – Stainless Steel Instrument and Medicine Cupboard
- TS 7011 – Stainless Steel Operation Theatre Cupboard
- TS 7012 – Stainless Steel Endoscopy Cabinet
- TS 7013 – Stainless Steel Medicine Cupboard with Plastic Containers
- TS 7014 – Stainless Steel Cap, Bonnet and Mask Cupboard
- TS 7015 – Stainless Steel Cupboard with Sliding Doors / Wall Mountable
- TS 7016 – Stainless Steel Cupboard / Medical Floor Type
- TS 7020 – Stainless Steel Double Morgue Unit / Front Access
- TS 7021 – Stainless Steel Double Morgue Unit / Side Access
- TS 7030 – Stainless Steel Autopsy Table
- TS 7040 – Stainless Steel Surgical Scrub Unit / Single Sink
- TS 7041 – Stainless Steel Surgical Scrub Unit / Double Sink
- TS 7050 – Stainless Steel Plaster Preparation Table
- TS 7051 – Stainless Steel Falcate Table
- TS 7052 – Stainless Steel Infant Washing Table
- TS 7054 – Stainless Steel Medical Liquid Waste Discharging Sink



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- TS 7055 – Stainless Steel Tool Washing Unit / Double Sink
- TS 7056 – Stainless Steel Tool Washing Unit / Single Sink
- TS 7060 – Stainless Steel Instrument Trolley / 3 Shelves
- TS 7061 – Stainless Steel Instrument Trolley / 2 Shelves
- TS 7062 – Stainless Steel Instrument Trolley with Drawer
- TS 7063 – Stainless Steel Instrument Trolley with Barriers
- TS 7064 – Stainless Steel Instrument Carriage and Storage Trolley
- TS 7065 – Stainless Steel Linen Trolley
- TS 7066 – Stainless Steel Laundry Trolley
- TS 7067 – Stainless Steel Medical Wastage Trolley
- TS 7068 – Stainless Steel Sterile Container Transport Trolley
- TS 7069 – Stainless Steel Container and Basket Transport Trolley
- TS 7070 – Stainless Steel Wire Basket Trolley
- TS 7071 – Stainless Steel Wire Basket Trolley / 3 Baskets
- TS 7072 – Stainless Steel Wire Basket Trolley / 6 Baskets
- TS 7073 – Stainless Steel Sponge Hanger Trolley
- TS 7074 – Stainless Steel Manual Adjustable Mayo Table
- TS 7075 – Stainless Steel Hydraulic Adjustable Mayo Table
- TS 7076 – Stainless Steel Bowl Stand / Single
- TS 7077 – Stainless Steel Bowl Stand / Double
- TS 7078 – Stainless Steel Medical Waste Bucket
- TS 7079 – Stainless Steel Mobile Monitor Stand
- TS 7080 – Stainless Steel Escabo – 1 Step
- TS 7081 – Stainless Steel Escabo / 2 Steps
- TS 7082 – Stainless Steel Waste Bin
- TS 7084 – Stainless Steel Hydraulic Stand Basin / 4 Castors
- TS 7085 – Stainless Steel Cage Trolley
- TS 7090 – Stainless Steel Shelving Unit
- TS 7091 – Stainless Steel Shelving Unit / Wire Shelves
- TS 7095 – Stainless Steel Packaging Table
- TS 7150 – Stainless Steel Working Table with Drawers and Cabinet
- TS 7151 – Stainless Steel Working Table with Drawers
- TS 7152 – Stainless Steel Working Table
- TS 7153 – Stainless Steel Basket for Steam Sterilizer
- TS 7160 – Stainless Steel Medical Linen Hamper
- TS 7161 – Stainless Steel Instrument Trolley / 2 Drawers
- TS 7166 – Stainless Steel Laundry Trolley with Lids
- TH 6000 – Electronic Examination Table

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- TH 6001 – Hydraulic Examination Table
- TH 6002 – Hydraulic Examination Table with Trendelenburg Movement
- TH 6004 – Examination Table with Castors
- TH 6009 – Examination Table
- TH 6010 – Examination Table with Drawers
- TH 6011 – Foldable Examination Table
- TH 6110 – Stool with Backrest
- TH 6111 – Stool
- TH 6115 – Wooden Chair with Armrests
- TH 6213 – Metallic Waiting Bench / Double
- TH 6214 – Metallic Waiting Bench / Triple
- TH 6317 – Escabo / Double Step
- TH 6417 – Escabo / Single Step
- TH 6420 – Metallic Locker / Double
- TH 6430 – Metallic Locker / Triple
- TH 6440 – Metallic Locker / Quadruple
- TH 6460 – Metallic Locker / Sestet
- TH 7009 – Metallic Instrument and Medicine Cupboard
- TH 7010 – Metallic Instrument and Medicine Cupboard
- TH 7012 – Metallic File Cupboard / 2 Doors
- TH 7013 – Metallic Instrument and Medicine Cupboard
- TH 7060 – Metallic Instrument Trolley
- TH 7061 – Metallic Instrument Trolley
- TH 7065 – Metallic Linen Trolley
- TH 7082 – Waste Bin / 15 L.
- TH 7083 – Waste Bin / 50 L
-

Description and Function

Designation:

Açıklama ve İşlev

Tanımı:

Classification of the Product as the Medical Device:

Ürünlerin Tıbbi Cihaz Olarak Sınıflandırılması

Medical Furniture

Medikal Mobilya

Class I – Non Sterile / EN 60601-1: 2006 + A1: 2013 + A12: 2014 - EN6061-2-52: 2010 + A 1: 2015

Sınıf I – Steril Olmayan / EN 60601-1: 2006 + A1: 2013 + A12: 2014 - EN6061-2-52: 2010 + A 1: 2015



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A) Declaration / Deklarasyon

T-HEALTH declares that the said products are safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

Sözü edilen ürünlerin, talimatlara uygun olarak ortak kullanım koşulları altında güvenli olduğunu ve paragraf B'de belirtildiği üzere, ilgili tüm yönergelerin temel gereklilikleriyle piyasaya sürülen tüm ürünlerin uygunluğunu sağlamak için alınmış tedbirleri T-HEALTH beyan eder.

B) Fulfilled technical requirements / Karşılanan teknik şartlar

These products' characteristics comply with the technical parameters related to it and stated in MDR 2017/745 as amended, which stipulates the technical parameters for healthcare products.

Bu ürünlerin özellikleri, ilgili tıbbi parametrelere uygundur ve MDR 2017/745'te sağlık ürünleri için teknik parametreleri belirleyen değişikliklerde belirtilmiştir.

C) Means of assessing conformity / Uygunluğu değerlendirilen araçlar

Conformity was assessed by the procedure stated MDR 2017/745

Uygunluk MDR 2017/745'te belirtilen prosedürle değerlendirildi.

D) Used standards / Kullanılan standartlar

The said products fulfills the requirements of these harmonized technical standards which were used for assessing of conformity: EN 60601-1: 2006 + A1: 2013 + A12: 2014, EN6061-2-52: 2010 + A 1: 2015, TS 4510, TS 5541, EN 6061-1-2, EN 60601-1, TS EN 60601-2-38, EN 60601-2-52, TS 4271, TSEK, TS 7167, TS 5539, TS6606, TS6607, EN 60601-1-2, TS EN 12727

Sözü edilen ürünler uygunluğun değerlendirilmesi için kullanılan uyumlu teknik standartların gerekliliklerini yerine getirmektedir: EN 60601-1: 2006 + A1: 2013 + A12: 2014, EN6061-2-52: 2010 + A 1: 2015, TS 4510, TS 5541, EN 6061-1-2, EN 60601-1, TS EN 60601-2-38, EN 60601-2-52, TS 4271, TSEK, TS 7167, TS 5539, TS6606, TS6607, EN 60601-1-2, TS EN 12727

Name: Alper TAŞ

Title: General Manager



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We, "T HEALTH MEDİKAL İÇ VE DİŞ TİC. LTD. ŞTİ. Manufacturer of hospital furniture and equipment , having factory at "Industrial Zone 1, Str. Nr: 66059, Bld. Nr: 30, Şehitkamil – Gaziantep / TÜRKİYE", assign Neotec SRL, based in Str I. Zaikin 37 , Chisinau MD -2005, Moldova, as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 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.

Place: Gaziantep / TÜRKİYE

Date: 28.09.2023

Signed: _____

 **T-HEALTH MEDİKAL**
İÇ VE DİŞ TİC. LTD. ŞTİ.
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