

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 7 din 08.06.2023

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. Canapea electrică de examinare YA-ET-D01

Se anexează următoarele acte:

1. Actul prin care producătorul își desemnează reprezentantul.
2. Declarație pe proprie răspundere
3. EC Declaration Of Conformity
4. EC Certificat

Data 08.06.2023

Semnatura_

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	

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. Canapea electrică de examinare YA-ET-D01

Sunt autentice și corespund realității.

Botnaru Andrei- Director

Numele, prenumele și funcția

Semnătura _____

Data 08.06.2023

Digitally signed by Botnaru Andrei
Date: 2023.06.08 14:38:33 EEST
Reason: MoldSign Signature
Location: Moldova



ZHANGJIAGANG MEDI MEDICAL EQUIPMENT CO.,LTD

Add: NO. 3 Jinxiu Road, Jinfeng Industrial Zone,

Jinfeng Town, Zhangjiagang City, Jiangsu Province, China 215600

Email: info@medik-medical.com

Web: www.medik-medical.com

TEL:+86-512-58688450



Declaration Letter

We, ZHANGJIAGANG MEDI MEDICAL EQUIPMENT CO., LTD.,

based in No. 3 Jinxiu road, Jinfeng Industry zone, Zhangjiagang China 215600, 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: Zhangjiagang China

Date: 07-Jun-2023

Signed: Eric CC



Digitally signed by Botnaru Andrei
Date: 2023.06.08 14:37:52 EEST
Reason: MoldSign Signature
Location: Moldova





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH

Harffstr. 47, 40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417:2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 60601-2-52:2010/A1:2015

EN 60601-1:2006/ A2:2020

EN 60601-1-2:2015/A1:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080601-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Digitally signed by Botnaru Andrei
Date: 2023.06.08 14:15:42 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer

Name: Zhangjiagang Medi Medical Equipment Co., Ltd

Address: Room 614 of Guotai New World Square, No.19 of Renmin East Road, Yangshe Town, Zhangjiagang City, Jiangsu Province, China

SRN:

Product Information

Name: Electric Hospital Bed

Model : YA-D7-3, YA-D8-2, YA-D7-2, YA-D8-1, YA-D5-12, YA-D5-7, YA-PD5-1, YA-D5-11, YA-D5-13, YA-D5-1, YA-D6-1, YA-D5-3, YA-D5-4, YA-D5-5, YA-D3-1, YA-D3-3, YA-D5-9, YA-D3-4, YA-DH6-1, YA-DH5-3, YA-DH5-1, YA-DH5-2, YA-DH3-2, YA-ET-D01, YA-ET-H02

EMDN: V080601

Basic UDI-DI: /

Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature

Date: 2023/4/24



Position: GM

Place: Zhangjiagang/China



Digitally signed by Botnaru Andrei
Date: 2023.06.09 14:38:17 EEST
Reason: MoldSign Signature
Location: Moldova



Compliance Report

Applicant: Zhangjiagang Medi Medical Equipment Co.,Ltd.
Address: No.3 Jinxiu Road, Jinfeng Industrial Zone, Jinfeng
Town, Zhangjiagang City, Jiangsu Province,
China
Product: Electric Hospital Bed, Manual Hospital Bed, Patient Transfer
Stretcher, Gynecology and Obstetric Table, Surgical Lamp,
Surgical Table
Type: See annex for details
Product Classification: Class I according to Rule 13 of MDR Annex VIII

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I ,II,III & IV of REGULATION (EU) 2017/745

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU REGULATION have and continue to be met.

No. 03259

Initial Issue Date: 21 April 2021

Signer



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The report information can be found on, WWW.SNQA.COM.CN.



Annex to Report (No. 03259)

Zhangjiagang Medi Medical Equipment Co.,Ltd.

Product Name	Type
Electric Hospital Bed	YA-D9-1,YA-D8-1,YA-D8-2,YA-D7-1,YA-D6-1,YA-D6-2, YA-D5-1,YA-D5-2,YA-D5-3,YA-D5-10,YA-D5-11,YA-D5-12, YA-D3-1,YA-D3-2,YA-D3-3,YA-D3-4,YA-D3-5,YA-D3-6, YA-D2-1,YA-DH6-1,YA-DH5-1,YA-DH5-2,YA-DH3-1, YA-PD5-1,YA-PD3-1,YA-D5-4,YA-D5-5,YA-D5-13
Manual Hospital Bed	YA-M5-1,YA-M5-2,YA-M3-1,YA-M3-2,YA-M2-1,YA-M2-3, YA-M2-4,YA-M2-5,YA-M2-6,YA-M2-7,YA-M2-8,YA-M1-1, YA-M1-2,YA-M1-3,YA-M0-1,YA-M0-2,YA-PM3-1,YA-PM2-1, YA-PM1-2,YA-PM0-1,MK-B02,MK-B04
Patient Transfer Stretcher	YA-PS01,YA-PS02,YA-PS03,YA-PS06,YA-PS07,YA-PS04, YA-PS05,YA-PS08,YA-PS09,YA-PS10,YA-PS11,YA-PS12, YA-PS13,YA-PS14,YA-CS01,YA-CS02,I-move
Gynecology and Obstetric Table	MC-C01,MC-C02,MC-C03,MC-C03S,MC-C04,MC-C05, MC-C06,MC-C07,MC-C08,MC-C09,MC-C10,MC-C11, MC-C12,MC-C13,MC-C14,MC-C15,MC-H02,MC-H04, MC-D03,MC-D04,MC-D05,MC-D08,MC-D09,MC-D10, MC-D11,MC-H01,MC-H03,MC-D01,MC-D02,MC-D06, MC-D07
Surgical Lamp	MK-D700HS,MK-D500HS,MK-D700/500HS, MK-D700/700HSMK-D700WY,MK-D500WY, MK-D700/500WY,MK-D700/700WYMK-D700BW, MK-D500BW,MK-D700/500BW, MK-D700/700BWMK-D700ZF,MK-D500ZF,MK-D700/500ZF, MK-D700/700ZFMKDL500WY,MK-DL260WY, MK-DL200WY,MK-DL100HF,MK-DL500ZF, MK-M25LZF,MK-DL200BW
Surgical Table	YA-01E,YA-02E,YA-03E,YA-04E,YA-05E,YA-06E,YA-07E, YA-08E,YA-07EH,YA-08EH,YA-01M,YA-02M, YA-03M,YA-04M,YA-05M,YA-06M,YA-07M,YA-08M

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Annex to Report (No. 03259)

Zhangjiagang Medi Medical Equipment Co.,Ltd.

Product Name	Type
Medical Chair	YA-DS-D02,YA-DS-D03,YA-DS-D04,YA-DS-D09, YA-DS-D10,YA-DS-M01,YA-DS-M02,YA-DS-M03, YA-DS-M04,YA-DS-M05,YA-DS-H01,YA-DS-R01, YA-DS-R02,YA-DS-R03,MK-F01,MK-F02,YA-S01,YA-S02, YA-S03,YA-S04,YA-FS01,MK-A06
Medical Trolley	MK-P01,MK-P02,MK-P03,MK-P04,MK-P06,MK-P07,MK-P11 MK-P18,MK-C01,MK-C02,MK-PC01,MK-PC02,MK-PC03 MK-S01,MK-S02,MK-S04,MK-S05,MK-S06,MK-S07,MK-S08, MK-S12,MK-S12,MK-S18,MK-S22,MK-S23,MK-S33,MK-S34
Examination Bed	YA-EC-M01,YA-EC-M02,YA-EC-M03,YA-EC-S02, YA-EC-S03,YA-EC-B01,YA-ET-D01,YA-ET-D02,YA-ET-D03 YA-EC-U01,YA-EC-U03,YA-EC-U05

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