

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 7 din 03.07.2023

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 pediatric standard YA-M3-1

Se anexează următoarele acte:

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

Data 03.07.2023

Digitally signed by Botnaru Andrei
Date: 2023.06.14 14:20 EEST
Reason: MoldSign Signature
Location: Moldova



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: „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 pediatric standard YA-M3-1

Sunt autentice și corespund realității.

Botnaru Andrei- Director

Numele, prenumele și funcția

Semnătura _____

Data 03.07.2023

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: 2023.06.15 20:07:42 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

TEL:+86-512-58688450

Email: info@medik-medical.com

EC Declaration of Conformity

Manufacturer

Zhangjiagang Medi Medical Equipment Co.,Ltd.

3 Jinxiu Road, Jinfeng Town, Zhangjiagang City, Jiangsu

Prov, China

We, the manufacturer. herewith declare the following

Product	Model
Hospital BED	YA-M3-1

UMDNS-Code:10-789

Meet the provisions of Directive 93/42/EEC (amended by 2007/47/EC) which apply to them.

The medical device has been assigned to (**Class I**) according to Annex IX of the Directive 93/42/EEC. It bears the mark.



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC (amended by 2007/47/EC).

Conformity assessment routs: annex VII of Directive 93/42/EEC (amended by 2007/47/ EC)

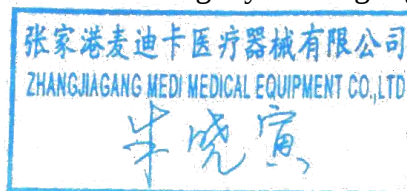
The above mentioned declaration of conformity is exclusively under the responsibility of **Zhangjiagang Medi Medical Equipment Co., Ltd.**

Place, Date

07-JUN-2023

EC Declaration of Conformity
CE-03

Legally Binding Signature, Function



Digitally signed by Botnaru Andrei
Date: 2023.06.20 15:56:52 EEST
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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

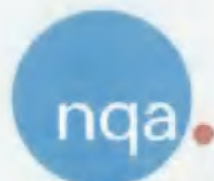
Permy Bao

Signer



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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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