

Către Agenția Medicamentului și Dispozitivelor Medicale

NOTIFICARE

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

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.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
producătorului **Hangzhou Kangji Medical Instrument Co., Ltd., China:**

- Clip din titan, L
- Clip din titan, M/L
- Clip din titan, M
- Clip din titan, S
- Clip din plastic, XL
- Clip din plastic, L
- Clip din plastic, M/L

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).



Data **14.09.2023**

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	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**
Chisinau, Republica Moldova,

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 dispozitivelor medicale ale producătorului producătorului

Hangzhou Kangji Medical Instrument Co., Ltd., China:

- Clip din titan, L
- Clip din titan, M/L
- Clip din titan, M
- Clip din titan, S
- Clip din plastic, XL
- Clip din plastic, L
- Clip din plastic, M/L

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătura



Data 14.09.2023

Date: Sept. 7th, 2023

LETTER OF AUTHORIZATION

We, HANGZHOU KANGJI MEDICAL INSTRUMENT CO., LTD.,

based in No. 1668 Chunjiang East Road Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311501, China, assign **Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as authorized representative in correspondence with the conditions of MDD 93/42/EEC.

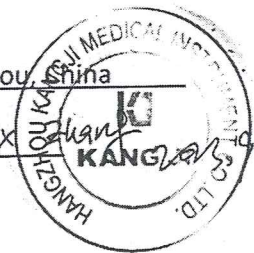
We declare that the company mentioned above is authorized to sale and after-sales service, of following medical devices on the territory of the Republic of Moldova.

No.	Medical Device Name
1	Disposable Ligation Clips (Metallic and Non-Metallic)
2	Clip Appliers

This letter of Authorization is valid until Dec. 31th,2024.

Place: Hangzhou, China

Signed: Phoenix Zhang 9.7





EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147407 0001

Report No.: 15054468 010

Manufacturer: Hangzhou Kangji
Medical Instrument Co., Ltd.
No. 1668 Chunjiang East Road, Economic
Development Zone, Tonglu
Hangzhou
311501 Zhejiang
P.R. China



Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: HD 60117691 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-03-05

Date: 2020-03-05

Notified Body

Jason Pan
Jason Pan



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60147407 0001
Report No.: 15054468 010

Manufacturer: Hangzhou Kangji
Medical Instrument Co., Ltd.
No. 1668 Chunjiang East Road, Economic
Development Zone, Tonglu
Hangzhou
311501 Zhejiang
P.R. China

Products:

- Non-sterile Reusable Electrosurgical Electrodes
- Electrosurgical Electrodes for Single Use
- Disposable Veress Needles
- Disposable Trocars
- Disposable Ligation Clips (Metallic and Non-Metallic)
- Rigid Endoscopes
- Disposable Suction and Irrigation Sets
- Disposable Uterine Manipulator and Vaginal Delineators
- Reusable Uterine Manipulator and Vaginal Delineators
- Specimen Retrieval Bags
- Disposable S.I.L.S. Ports
- Disposable Suction Tubes



Notified Body

Date: 2020-03-05

Jason Pan

Jason Pan



EC Declaration of Conformity

Manufacturer:

Hangzhou Kangji Medical Instrument Co.,Ltd
No.1668 Chunjiang East Road,Economic
Development Zone
Tonglu, Hangzhou, Zhejiang ,311501,China

whose single Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10,
1e Verd, 2595AA, The Hague, Netherlands

We, the manufacturer, herewith declare that the products

Disposable ligation clips (metallic clips and non-metallic clips)

GMDN-Code/Preferred Terms: 35649, 56711,



meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class II b according to Annex IX rule 8 of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

To have established and to maintain a proper procedure to guarantee the after-sales surveillance, as prescribed by MDR 2017/ 745. The original documentation is filed in the head office of the company.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60147407 0001
Issue date: 2020-03-05
Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hangzhou Kangji Medical Instrument Co., Ltd
Address: No.1668 Chunjiang East Road, Economic Development Zone Tonglu,
Hangzhou, Zhejiang ,311501,China

Hangzhou, 2021-04-20

Place, date

A handwritten signature in black ink, appearing to be "程 达" (Cheng Da).

Legally binding signature, Function

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Clip din titan		L	
2		Clip din titan		M/L	
3		Clip din titan		M	
4		Clip din titan		S	
5		Clip din plastic		XL	
6		Clip din plastic		L	
7		Clip din plastic		M/L	

