Către Agenţia Medicamentului şi 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 şi 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 | |

Digitally si
Date: 2023.
Reason: Mo
Location: M

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. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului 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 şi funcţia:*

*RA-Manager – Sandu Irina*

*Semnătura* _____

*Data* ~~14.09.2023~~

KANGJI康基

Enlightening
the Life

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

HANGZHOU KANGJI MEDICAL INSTRUMENT CO., LTD.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, MUN. CHIȘINĂU
S.R.L.
"DITA ESTFARM"
IDNO 1002600046359

杭州康基医疗器械有限公司
Hangzhou Kangji
Medical Instrument Co., LTD.

浙江省杭州市桐庐县桐庐经济开发区春江东路 1668 号
No.1668, Chunjiang East Road, Economic DevelopmentZone
Tonglu, Hangzhou, Zhejiang 311501, China

T: 010-58256997
E: kangji@hzkangji.com
F: 0571-64622980

# EC Certificate

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

TÜVRheinland®

**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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland III

**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.

TÜVRheinland®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**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

S.R.L. "DITA ESTFARM" IDNO 1002600046359 SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, MUN. CHIȘINĂU 18

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**

Jason Pan

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

**Date:** 2020-03-05

Ver.: B/5

# 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 IIb 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*

*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 | |