

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@ditamd.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 **Taizhou Kangjian Medical Equipment Co., Ltd., China:**

- Set ginecologic XS
- Set ginecologic S
- Set ginecologic M
- Set ginecologic M/L
- Set ginecologic 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 **12.09.2023**

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. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului **Taizhou Kangjian Medical Equipment Co., Ltd., China:**

- Set ginecologic XS
- Set ginecologic S
- Set ginecologic M
- Set ginecologic M/L
- Set ginecologic L

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția:*

*RA-Manager – Sandu Irina*

*Semnătura*



*Data* **12.09.2023**



台州康健医用器械有限公司

**TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO., LTD**

浙江省玉环市机电工业园区

ADD:THE MACHINE ELECTRICITY ZONE OF YUHUAN CITY

ZHEJIANG PROVINCE 317600, P.R.CHINA

TEL:0086-576-87225930

FAX:0086-576-87239885

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We, **TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO., LTD**

based in THE MACHINE ELECTRICITY ZONE OF YUHUAN CITY,ZHEJIANG PROVINCE 317600, P.R.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 Regulation (EU) 93/42.

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:TAIZHOU,CHINA

Date: 11-SEP-2023

Signed:





**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60156376 0001

**Report No.:** 15085363 008

**Manufacturer:** Taizhou Kangjian Medical Equipments Co., Ltd.  
The Machine Electricity Zone (Hang Ni Kan) of Yuhuan County  
Zhejiang Province 317600  
P.R. China



**Products:** Medical Devices  
(see attachment for products and additional site included)  
Replaces Approval, Registration No.: DD 60147806 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2021-04-28

**Date:** 2021-04-28

Notified Body  
  
Fuxiu Sheng

**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.



Doc. 1/1, Rev. 0

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

Attachment to  
Certificate

Registration No.: DD 60156376 0001  
Report No.: 15085363 008

Manufacturer: Taizhou Kangjian Medical  
Equipments Co., Ltd.  
The Machine Electricity Zone  
(Hang Ni Kan) of Yuhuan County  
Zhejiang Province 317600  
P.R. China



Products:

Disposable Cervical Brushes, Disposable Cervical Spatulas,  
Disposable Cervical Cell Sampling Spoons, Disposable  
Gynecological Sets, Oxygen Masks, Non Rebreathing Masks,  
Nebulizer Masks, Venturi Masks, Nebulizer with Mouthpieces,  
Nasal Oxygen Cannulae;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Sterile Vaginal Speculums for Single Use, Disposable  
Anoscopes, Disposable Nasal Speculums, Disposable  
Tongue Depressors, Plastic Forceps

Site included:

Qiaotian Community (Tiantong Road West) of Tongcheng Town,  
Tianchang City, Anhui Province 239311, China

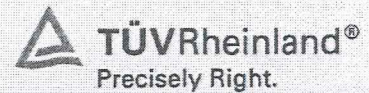
Date: 2021-04-28

Notified Body

Fuxiu Sheng



**Business Stream Products  
Certification Department**



TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Taizhou Kangjian Medical  
Equipments Co., Ltd.  
The Machine Electricity Zone  
(Hang Ni Kan) of Yuhuan County  
ZHEJIANG PROVINCE 317600  
P.R. CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date April 30, 2021

**Application for** : QMS Produktion, Anhang V MDD  
**Certificate No.** : DD 60156376 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : Richtlinie 93/42/EWG



Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60156376 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490

台州康健医用器械有限公司  
Taizhou Kangjian Medical Equipment Co., Ltd.

**EC DECLARATION OF CONFORMITY**

Document number: TKY/CE-TD-GS-18

Name and address of the manufacturer: Taizhou Kangjian Medical Equipment Co., Ltd.  
Address: The machine electricity zone (Hang Ni Kan) of Yuhuan county, Zhejiang province 317600, China  
Branch company address: Qiatian Community (Tiantong Road West) of Tongcheng Town, Tianchang City, Anhui Province 239311, China

We declare under our sole responsibility that  
the medical device: **Disposable gynecological set**  
Modle: According the requirements of the Customers  
of class: **IIa Sterile medical devices**

According to MDD 93/42/EEC Annex IX Rule 6, the Disposable Gynecological Set belong to class IIa Sterile medical devices.

Meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex v**

Registration No.: **DD 60156376 0001**

Notified Body: **TÜV Rheinland LGA Products GmbH**  
Tillystraße 2  
90431 Nürnberg  
Deutschland  
CE 0197



*Yuhuan, 2021-09-10*

Place, date



Name and function

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Speculă vaginală sterilă		XS	
2		Speculă vaginală sterilă		S	
3		Speculă vaginală sterilă		M	
4		Speculă vaginală sterilă		M/L	
5		Speculă vaginală sterilă		L	

