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 **Suzhou Yudu Medical Co., Ltd., China:**

- Cateter de aspirație (Conform Anexei 3)
- Cateter Nelaton (Conform Anexei 3)
- Cateter Levin (Conform Anexei 3)

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 **15.09.2023** 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[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului producătorului **Suzhou Yudu Medical Co., Ltd., China:**

- Cateter de aspirație (Conform Anexei 3)
- Cateter Nelaton (Conform Anexei 3)
- Cateter Levin (Conform Anexei 3)

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia: *Semnătura* _____

RA-Manager – Sandu Irina *Data* ***15.09.2023***

Suzhou Yudu Medical Equipment Co., Ltd

Eastern xinzhuang(zhangqiao) town, Changshu, Jiangsu, China

We, Suzhou Yudu Medical Equipment Co., Ltd ,

based in Eastern xinzhuang(zhangqiao) town, Changshu, Jiangsu, 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 MDD 93/42/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:_____ Date: Sep 13th, 2023

Signed:

DNV·GL

EC CERTIFICATE

Production Quality Assurance

Certificate No.:	Project No.:	Valid Until:
9930-2017-CE-RGC-NA-PS	PRJC-44566-2008-PRC-RGC	27 May 2024

This is to certify that the quality system of:

Suzhou Yudu Medical Co., Ltd.

Eastern Xinzhuang (Zhangqiao) Town, 215552 Changshu, China

For production and final product inspection/testing of:
DISPOSABLE MEDICAL DEVICES

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX V OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 10 June 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
9930-2017-CE-RGC-NA-PS

Project No.:
PRJC-44566-2008-PRC-RGC

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	10 June 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Disposable Urethral Catheter	F6, F8, F10, F12, F14, F16, F18, F20, F22, F24, F26, F28, F30	IIa
Disposable Suction Catheter	F6, F8, F10, F12, F14, F16, F18, F20	IIa
Disposable Feeding Tube	F8, F10, F12, F14, F16, F18, F20, F22	IIa
Disposable Nasal Oxygen Cannula	Large, Medium, Small	IIa
Disposable Stomach Tubes	F8, F10, F12, F14, F16, F18, F20, F22, F24	IIa
Disposable Rectal Tubes	F24, F26, F28, F30	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Suzhou Yudu Medical Co., Ltd.	Eastern Xinzhuang (Zhangqiao) Town, 215552 Changshu, China

EU Representative
Wellkang Ltd t/a Wellkang Tech Consulting, Suite B, 29 Harley Street, LONDON W1G 9QR, United Kingdom

Certificate No.:	Project No.:	Valid Until:
9930-2017-CE-RGC-NA-PS	PRJC-44566-2008-PRC-RGC	27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Declaration of Conformity

For the following products:

Disposable Suction Catheter

(Product Name)

F6, F8, F10, F12, F14, F16, F18, F20

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable harmonized standards are:

EN ISO13485:2016, EN ISO 14971:2012, EN ISO 10993-l:2009/AC:2010,
EN ISO 10993-5: 2009, EN ISO 11135-1:2007, EN ISO 11737-1: 2006. EN 62366:2008
EN ISO 15223-l:2016. EN 1041:2008

Conformity Assessment Route:

Annex V of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:

Company Name: Wellkang Ltd t/a Wellkang Tech Consulting

Company Address: Suite B, 29 Harley Street, LONDON WlG 9QR,England,United Kingdom

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Suzhou Yudu Medical Equipment Co., Ltd

Company Address: Eastern xinzhuang(zhangqiao) town, Changshu, Jiangsu, China

Tao Wei Qing
(Legal Signature)

General Manager
(Position/title)

2019.11.23
(Date)

Declaration of Conformity

For the following products:

Disposable Urethral Catheter

(Product Name)

F6, F8, F10, F12, F14, F16, F18, F20, F22, F24, F26, F28, F30

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Standard Applied:
EN ISO 13485:2016,EN ISO 14971:2012,EN 1616:1997,EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009,EN ISO 11135-1:2007,EN ISO 11737-1:2006,EN 62366:2008, EN ISO15223-1:2016,EN 1041:2008

Conformity Assessment Route:
Annex V of Medical Device Directive

Notified Body:
DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:

Company Name: Wellkang Ltd t/a Wellkang Tech Consulting

Company Address: Suite B, 29 Harley Street, LONDON W1G 9QR, England, United Kingdom

The following manufacturer is responsible for making this declaration:

Company Name:Suzhou Yudu Medical Equipment Co., Ltd

Company Address: Eastern xinzhuang(zhangqiao)town, Changshu, Jiangsu, China

Tao weiQing
(Legal Signature)

General Manager
(Position/title)

2019.11.23
(Date)

Declaration of Conformity

For the following products:

Disposable Stomach Tube

(Product Name)

F8, F10, F12, F14, F16, F1 8, F20, F22, F24

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable harmonized standards are:

EN ISO13485:2016, EN ISO 14971:2012, EN ISO 10993-l:2009/AC:2010,
EN ISO 10993-5: 2009, EN ISO 11135-1:2007, EN ISO 11737-1: 2006. EN 62366:2008
EN ISO 15223-l:2016. EN 1041:2008

Conformity Assessment Route:

Annex V of Medical Device Directive

Notified Body:

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The following manufacturer is exclusively responsible for making this declaration:

Company Name: Suzhou Yudu Medical Equipment Co., Ltd

Company Address: Eastern xinzhuang(zhangqiao) town, Changshu, Jiangsu, China

Tao Wei Qing
(Legal Signature)

General Manager
(Position/title)

2019.11.23
(Date)

Anexa 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Cateter de aspirație		6Fr	
2		Cateter de aspirație		8Fr	
3		Cateter de aspirație		10Fr	
4		Cateter de aspirație		12Fr	
5		Cateter de aspirație		14Fr	
6		Cateter de aspirație		16Fr	
7		Cateter de aspirație		18Fr	
8		Cateter de aspirație		20Fr	
9		Cateter Nelaton		6Fr	
10		Cateter Nelaton		8Fr	
11		Cateter Nelaton		10Fr	
12		Cateter Nelaton		12Fr	
13		Cateter Nelaton		14Fr	
14		Cateter Nelaton		16Fr	
15		Cateter Nelaton		18Fr	
16		Cateter Nelaton		20Fr	
17		Cateter Nelaton		22Fr	
18		Cateter Nelaton		24Fr	
19		Cateter Nelaton		26Fr	
20		Cateter Nelaton		28Fr	
21		Cateter Nelaton		30Fr	
22		Cateter Levin		8Fr	
23		Cateter Levin		10Fr	
24		Cateter Levin		12Fr	
25		Cateter Levin		14Fr	
26		Cateter Levin		16Fr	
27		Cateter Levin		18Fr	
28		Cateter Levin		20Fr	
29		Cateter Levin		22Fr