

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 **Guangdong Ecan Medical Co., Ltd., China:**

- Cateter Foley (conform Anexei 3)
- Tub traheostomic (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 **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. 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 producătorului

**Guangdong Ecan Medical Co., Ltd., China:**

- Cateter Foley (conform Anexei 3)
- Tub traheostomic (conform Anexei 3)

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția:*

*RA-Manager – Sandu Irina*

Semnătura \_\_\_\_\_



Data **14.09.2023**

Ecan Medical Co., Ltd.

Address: 1710#, No.2218 Hunan RD, Pudong District Shanghai 201204 P.R.C  
Tel: 00 86 21 5056 7018 Fax: 00 86 21 5056 7019

ECAN

We, Guangdong Ecan Medical Co., Ltd.,

based in Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua

District, Guangzhou, Guangdong, 510920, P.R. China,

assign Dita EstFarm SRL, based in Str. Burebista 23, Chisinau, MD -2032,

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: Guangzhou

Date: March 30<sup>th</sup> 2023

Signed: C. Jin



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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



# EC Certificate

Full Quality Assurance System  
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
 (Devices in Class IIa, IIb or III)

**No. G1 104589 0002 Rev. 00**

**Manufacturer:** **Guangdong Ecan Medical Co., Ltd.**  
 Building 1, No. 222, Xindu Road, Chengjiao Street  
 Conghua District  
 510920 Guangzhou City, Guangdong Province  
 PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** Urethral catheters, Laryngeal Mask Devices,  
 Endotracheal Tubes, Tracheostomy Tubes,  
 Endobronchial Tubes, Feeding Tubes, Suction  
 Catheters, Suction tubing,  
 PVC Stomach Tubes, Oxygen Masks,  
 Tubing Set for Nebulizers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** GZ1942901

**Valid from:** 2019-11-26  
**Valid until:** 2024-05-26

**Date,** 2019-11-26

Christoph Dicks  
 Head of Certification/Notified Body



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Product Service

# EC Certificate

Full Quality Assurance System  
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
 (Devices in Class IIa, IIb or III)

**No. G1 104589 0002 Rev. 00**


## Facility(ies):

Guangdong Ecan Medical Co., Ltd.  
 Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua  
 District, 510920 Guangzhou City, Guangdong Province,  
 PEOPLE'S REPUBLIC OF CHINA



TÜV SÜD  
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT

Catolita Foley,  
Dita

	Doc. No.: YK/CE13-01	Edition: A/0
	<b>Urethral Catheter CE Declaration of Conformity</b>	Effective Date: 2019-11-26
		Page: 1 / 1

### Declaration of Conformity

**Manufacturer:**

Name: Guangdong Ecan Medical Co., Ltd.

Add: Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, 510920, Guangzhou City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Tel: 00 86 20 3750 1359 Fax: 00 86 20 3750 1359

**European Representative:**

Name: Zoustech S.L

Address: Pso.Castellana,141-Planta 19,28046-Madrid, Spain

Tel: +34-40-2513175 Fax: +34-40-255726

**Product Name:** Urethral Catheter (Latex foley catheter, Silicone foley catheter)



Classification and relevant Rule of MDD: IIb MDD Annex IX, rule 5  
The UMDNS code: 10762

**Types/Sizes:**

- 1) 2-way Paediatric (6FR/8FR/10FR)
- 2) 2-way Standard (12Fr/14Fr/16Fr/18Fr/20Fr/22Fr/24Fr/26Fr/28Fr/30Fr)
- 3) 3-way Standard (16Fr/18Fr/20Fr/22Fr/24Fr/26Fr/28Fr/30Fr)

Product Certification Conformity Assessment Route: Annex II.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

#### DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

Standard: All applicable harmonized Standard (published in the Official Journal of the European Communities) ENISO13485: 2003/AC: 2009, ENISO14971:2009, ENISO10993-1:2009, ENISO10993-5:2009, ISO 10993-7:2008, ENISO10993-10:2010, ENISO10993-11:2009, ENISO10993-12:2007, EN980:2008, EN1041:2008, EN556:2001, ENISO14155-1:2003, ENISO14155-2:2003, ISO14644-1:1999, ENISO11607-1:2009, ENISO11607-2:2009, ENISO11737-1:2006, ENISO11737-2:2006, ENISO11135-1:2007, ISO11138-1:2006, ISO11138-2:2006, EN 62366:2008, EN1616:1997, MEDDEV. 2.7.1 Rev.3

Notified Body: TÜV SÜD Product Service GmbH, Add: Ridlestrasse. 65,80339 München, Germany

Identification Number: 0123

CE Certificate No.: G1 104589 0002 Rev. 00

Valid until: 2024-05-26

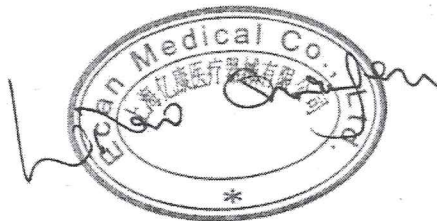
Signature of issue person:


Position: General Manager

Name: Mr. Liao Quangen

Date: May 26<sup>th</sup>, 2020

Place: Shanghai



	Doc. No.: YK/CE11-01	Edition: A/0
	<b>Tracheostomy Tube CE Declaration of Conformity</b>	Effective Date: 2019-11-26
		Page: 1 / 1

### Declaration of Conformity

**Manufacturer:**

Name: Guangdong Ecan Medical Co., Ltd.

Add: Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, 510920, Guangzhou City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Tel: 00 86 20 3750 1359

Fax: 00 86 20 3750 1359

**European Representative:**

Name: Zoustech S.L

Address: Pso.Castellana,141-Planta 19,28046-Madrid, Spain

Tel: +34-40-2513175

Fax: +34-40-255726

**Product Name:** Tracheostomy Tube



Classification and relevant Rule of MDD: II b MDD Annex IX, rule 5  
The UMDNS code: 35404

**Types/Sizes:**

1) Uncuffed (4.0 mm/4.5 mm/5.0 mm/5.5 mm/6.0 mm/6.5 mm/7.0 mm/7.5 mm/8.0 mm/8.5 mm/9.0 mm)

2) Cuffed (5.0 mm/5.5 mm/6.0 mm/6.5 mm/7.0 mm/7.5 mm/8.0 mm/8.5 mm/9.0 mm)

Product Certification Conformity Assessment Route: Annex II.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

### DIRECTIVES

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Notified Body: TÜV SÜD Product Service GmbH, Add: Ridlestrasse. 65,80339 München, Germany

Identification Number: 0123

CE Certificate No.: G1 104589 0002 Rev. 00

Valid until: 2024-05-26

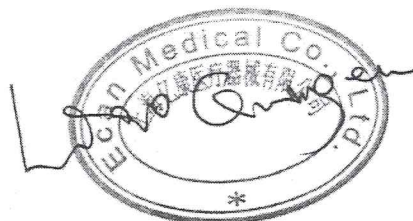
Signature of issue person:

Position: General Manager

Name: Mr. Liao Quangen

Date: May 26<sup>th</sup>, 2020

Place: Shanghai



Anexa 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Cateter Foley		cu 3 canale silicon, Dufour, 16Fr	
2		Cateter Foley		cu 3 canale silicon, Dufour, 18Fr	
3		Cateter Foley		cu 3 canale silicon, Dufour, 20Fr	
4		Cateter Foley		cu 3 canale silicon, Dufour, 22Fr	
5		Cateter Foley		cu 3 canale silicon, 16Fr	
6		Cateter Foley		cu 3 canale silicon, 18Fr	
7		Cateter Foley		cu 3 canale silicon, 20Fr	
8		Cateter Foley		cu 3 canale silicon, 22Fr	
9		Cateter Foley		cu 3 canale silicon, 24Fr	
10		Tub traheostomic		cu manșetă, 5,0mm	
11		Tub traheostomic		cu manșetă, 5,5mm	
12		Tub traheostomic		cu manșetă, 6,0mm	
13		Tub traheostomic		cu manșetă, 6,5mm	
14		Tub traheostomic		cu manșetă, 7,0mm	
15		Tub traheostomic		cu manșetă, 7,5mm	
16		Tub traheostomic		cu manșetă, 8,0mm	
17		Tub traheostomic		cu manșetă, 8,5mm	
18		Tub traheostomic		cu manșetă, 9,0mm	

