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 **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	

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

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

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia:

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

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 30th 2023

Signed:

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

Product Service S.R.L. "DITA ESTFARM" IDNO 1002600046359 CHIȘINĂU

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

TÜV SÜD 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

S.R.L. "DITA ESTFARM" IDNO 1002600046359 SOCIETATEA CU RASPUNDERE LIMITATA, REPUBLICA MOLDOVA, CHISINAU 18

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Catetru Foley, Dr.

Ecan Medical Co., Ltd.	Doc. No.: YK/CE13-01	Edition: A/0
	Urethral Catheter CE Declaration of Conformity	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 Münich, 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 26th, 2020

Place: Shanghai

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: Ⅱb 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

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 Münich, 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 26th, 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