

Agenția Medicamentului  
și Dispozitivelor Medicale

## NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 54 din 15.09.2023

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, mun.Chișinău, str.Academiei, 2, tel.:(022) 72-75-25/069501992, fax:(022) 73-83-42, e-mail: sognomd@gmail.com,  
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:

**Conform Anexei nr.3 "Lista dispozitivelor medicale Ningbo Luke Medical Devices Co. Ltd"**

Se anexează următoarele acte:

1. Certificat CE,
2. Declarație de Conformitate,
3. Scrisoarea autorizată a producătorului,
4. Declarație pe propria răspundere,
5. Lista dispozitivelor medicale.

Data: 15.09.2023



### 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: **FPC "SOGNO" SRL**, cu sediul m.Chîșinău, str. Academiei nr.2, 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:

**Conform Anexei nr.3 "Lista dispozitivelor medicale Ningbo Luke Medical Devices Co. Ltd"**

Sunt autentice și corespund realității.



Iarovoi Petru, Director

Semnătura

Data: 15.09.2023

**Lista dispozitivelor medicale Ningbo Luke Medical Devices Co. Ltd**

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod UMDNS
RETxxPC	TUB ENDOTRAHEAL ARMAT CU MANȘETĂ	—	PVC, dimensiuni 2.0 – 9.5	Dispozitiv terapeutic activ	14085

Iarovoi Petru, Director

Semnătura






## Ningbo Luke Medical Devices Co., Ltd.

Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China.

Web: [www.canack.com](http://www.canack.com)

Tel: +86-574-22661850

Mail: [info@canack.com](mailto:info@canack.com)

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We, Ningbo Luke Medical Devices Co., Ltd., based in Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China, assign FPC "SOGNO" SRL, based at No 2 Academiei str., Chisinau, Republic of Moldova, as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/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: Yuyao, China,      Date: 31.07.2023

Signature: \_\_\_\_\_

宁波路加医疗器械有限公司  
NINGBO LUKE MEDICAL DEVICES CO., LTD  
*Cheng Lu*



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



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 086250 0018 Rev. 01**

**Manufacturer:**

**Ningbo Luke Medical Devices Co., Ltd.**

Gujiayan, Yangming Road  
315400 Yuyao City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Product  
Category(ies):**

**Laryngeal Mask Airways,  
Stomach Tubes, Drainage Tubes,  
Endotracheal Tubes, Oxygen Masks,  
Suction Catheters, Nasal Oxygen Cannulas,  
Breathing Circuits,  
Heat and Moisture Exchangers,  
Breathing System Filters,  
Manual Resuscitators,  
Wound Drainage Systems,  
Infusion Sets with Precision Filters for Single-Use,  
Double Lumen Endobronchial Tubes,  
Single-Use Anesthesia Kits,  
Urinary Catheterization Collection Kits,  
Disposable Endobronchial Blocker Tubes,  
Anesthesia Masks, Catheter Mounts,  
Suction Tubing with Yankauer Handle,  
Nebulizer Masks, Tracheostomy Tubes.**

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

**Report No.:** SH19651EXT01

**Valid from:** 2020-01-08

**Valid until:** 2024-05-26

**Date,** 2020-01-08

Christoph Dicks  
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE

A4 / 07.17



Ningbo Luke Medical Devices Co., Ltd.	Document No.: LK-TF-05
	Version: 5
CE Technical File of Endotracheal Tubes	Issue date:2020-01-11

### 01 Declaration of Conformity

**Manufacturer:**

Name: Ningbo Luke Medical Devices Co.,Ltd.

Add: Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People' s Republic of China

European Representative:

Name :Shanghai International Holding Corp.GmbH(Europe)

Add : Eiffestrasse 80, 20537 Hamburg , Germany

Tel: + 49-40-2513175 Fax: + 49-40-255726

**Product Name:** Endotracheal Tubes

Object of the Declaration:

Item No.	Size (mm)	Item No.	Size (mm)	Item No.	Size (mm)	Item No.	Size (mm)	Item No.	Size (mm)
ET20P	2.0	ET20PC	2.0	RET20P	2.0	RET20PC	2.0	ETS20PC	2.0
ET25P	2.5	ET25PC	2.5	RET25P	2.5	RET25PC	2.5	ETS25PC	2.5
ET30P	3.0	ET30PC	3.0	RET30P	3.0	RET30PC	3.0	ETS30PC	3.0
ET35P	3.5	ET35PC	3.5	RET35P	3.5	RET35PC	3.5	ETS35PC	3.5
ET40P	4.0	ET40PC	4.0	RET40P	4.0	RET40PC	4.0	ETS40PC	4.0
ET45P	4.5	ET45PC	4.5	RET45P	4.5	RET45PC	4.5	ETS45PC	4.5
ET50P	5.0	ET50PC	5.0	RET50P	5.0	RET50PC	5.0	ETS50PC	5.0
ET55P	5.5	ET55PC	5.5	RET55P	5.5	RET55PC	5.5	ETS55PC	5.5
ET60P	6.0	ET60PC	6.0	RET60P	6.0	RET60PC	6.0	ETS60PC	6.0
ET65P	6.5	ET65PC	6.5	RET65P	6.5	RET65PC	6.5	ETS65PC	6.5
ET70P	7.0	ET70PC	7.0	RET70P	7.0	RET70PC	7.0	ETS70PC	7.0
ET75P	7.5	ET75PC	7.5	RET75P	7.5	RET75PC	7.5	ETS75PC	7.5
ET80P	8.0	ET80PC	8.0	RET80P	8.0	RET80PC	8.0	ETS80PC	8.0
ET85P	8.5	ET85PC	8.5	RET85P	8.5	RET85PC	8.5	ETS85PC	8.5
ET90P	9.0	ET90PC	9.0	RET90P	9.0	RET90PC	9.0	ETS90PC	9.0
ET95P	9.5	ET95PC	9.5	RET95P	9.5	RET95PC	9.5	ETS95PC	9.5

UMDNS Code: 14085

Classification (MDD, Annex IX): IIa

Classification and relevant Rule of MDD 93/42/EEC: Annex IX, Rule 7

Conformity Assessment Route: Annex V.3 of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively

Ningbo Luke Medical Devices Co., Ltd.	Document No.: LK-TF-05
CE Technical File of Endotracheal Tubes	Version: 5
	Issue date:2020-01-11

responsible for the declaration of conformity.

**DIRECTIVES**

**General Applicable Directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device(MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

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

Identification Number: CE0123

(EC) Certificate(s):G2 0862500018 Rev.01

Expire Date of the Certificate: 2024-05-26

Start of CE Marking: 2016-10-30

Place, Date of Issue: Yuyao

Signature: *chengliu*

Name: Cheng Liu

Position: **General Manager**