Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Agenţia Medicamentului
şi 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 şi 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

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 signed by Iarovoi Petru
Date: 2023.09.15 15:17:24 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m.Chişinău, str. Academiei nr.2, Republica Moldova, declar pe proprie răspundere, cunoscând prevederile art. **352**[1], Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivelor medicale:

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

Sunt autentice şi corespund realităţii.

Iarovoi Petru, Director *Semnătura* _____

Data: 15.09.2023

Anexa nr.3

Lista dispozitivelor medicale Ningbo Luke Medical Devices Co. Ltd

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod UMDNS
CM-E	CATETER MOUNT ADULT ȘI PEDIATRIC	—	Tub extensibil, cot 15F/22M, conector 22F, lungime 150mm	Dispozitiv terapeutic activ	15562

Iarovoi Petru, Director *Semnătura* _____

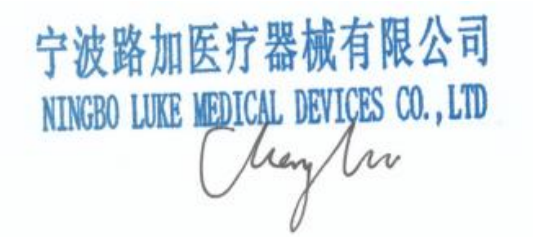
Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China.
Web: www.canack.com Tel: +86-574-22661850 Mail: info@canack.com

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: _____



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 Product Service GmbH is Notified Body with identification no. 0123

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

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A4 / 07.17

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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD
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

Facility(ies):

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

CANACK TECHNOLOGY LTD.
Room 1308-2, Building A, Huaxing Times Square, No. 478
Wensan Road, Xihu District, 310007 Hangzhou City, Zhejiang
Province, PEOPLE'S REPUBLIC OF CHINA

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

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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: Catheter Mounts

Object of the Declaration:

Item No.	Type
CM-C	Corrugated
CM-E	Expandable
CM-S	Smoothbore

UMDNS Code: 15562

Classification (MDD, Annex IX): IIa

Classification and relevant Rule of MDD 93/42/EEC: Annex IX, Rule 2

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 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: 2016-10-16

Place, Date of Issue:Yuyao

Signature: Cheng Liu

Name: Cheng Liu

Position: **General Manager**