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

Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 57 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 Nanchang Yili Medical Instrument 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 16:34:25 EEST
Reason: MoldSign Signature
Location: Moldova

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m.Chișinău, 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 și datele furnizate pentru notificarea dispozitivelor medicale:

Conform Anexei nr.3 "Lista dispozitivelor medicale Nanchang Yili Medical Instrument Co., Ltd."

Sunt autentice și corespund realității.

Iarovoi Petru, Director *Semnătura* _____

Data: 15.09.2023

Anexa nr.3

Lista dispozitivelor medicale Nanchang Yili Medical Instrument Co., Ltd

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
YL-SFC3D-18	CATETER URETRAL FOLEY CU TREI CĂI	EasyThru®	Silicon, vârf tip Dufour, balon 50ml, 18Fr	Dispozitiv terapeutic activ	34917
YL-SFC3D-20	CATETER URETRAL FOLEY CU TREI CĂI	EasyThru®	Silicon, vârf tip Dufour, balon 50ml, 20Fr	Dispozitiv terapeutic activ	34917
YL-SFC3D-22	CATETER URETRAL FOLEY CU TREI CĂI	EasyThru®	Silicon, vârf tip Dufour, balon 50ml, 22Fr	Dispozitiv terapeutic activ	34917
YL-SFC3D-24	CATETER URETRAL FOLEY CU TREI CĂI	EasyThru®	Silicon, vârf tip Dufour, balon 50ml, 24Fr	Dispozitiv terapeutic activ	34917

FIRMA DE PRODUCERE ȘI COMERT "SOGNO" S.R.L. • Sogno S.R.L. IDNO 1004600015854 REPUBLICA MOLDOVA, mun. CHIȘINĂU

Iarovoi Petru, Director *Semnătura* _____

Nanchang Yili Medical Instrument Co., Ltd

Add: Room 908, 101# Building, JLH605-B01 Greenland International Exp Center, Jiulong Road 1177, Honggutan District, Nanchang, Jiangxi, China

We, Nanchang Yili Medical Instrument Co., Ltd, based in **Room 908, 101# Building, JLH605-B01 Greenland International Exp Center, Jiulong Road 1177, Honggutan District, Nanchang, Jiangxi, 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.

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: Nanchang, China Date: 13.09.2023

NANCHANG YILI MEDICAL INSTRUMENT CO.,LTD
南昌市毅力医疗器械有限公司

Signature: Tenjsa Huang

黄浩娟

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146269 0001

Report No.: 50307115 002

Manufacturer:
Nanchang Yili Medical Instrument
Co., Ltd
Room 908, 101# Building, JLH605-B01
Greenland International Exp Center
Jiulong Road 1177, Honggutan District
330000 Nanchang, Jiangxi
P.R. China

Products: Sterile Urethral Catheters for Single Use

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-13

Date: 2020-04-13

Notified Body

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®
LGA
Precisely Right.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Nanchang Yili Medical Instrument
Co., Ltd
Room 908, 101# Building, JLH605-B01
330000 NANCHANG, JIANGXI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 13, 2020

Application for : **Vollst. QMS, Anhang II MDD**
Certificate No. : HD 60146269 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. HD 60146269 0001.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

EU Declaration of Conformity (DoC)

We

Company Name: *Nanchang Yili Medical Instrument Co., Ltd*
Postal Address: Room 908, 101# Building, JLH605-B01 Greenland International Exp Center, Jiulong Road 1177, Honggutan District, Nanchang, Jiangxi, China
Postcode: 330000
City: Nanchang
Telephone Number: +86-791-88252326
eMail address: sales@yilimed.com

Whose single authorised EU Representative

EU Representative Name: *Luxus Lebenswelt GmbH*
EU Representative Postal Address: Kochstr. 1, 47877, Willich, Germany
EU Representative Postcode:
EU Representative City: Willich
EU Representative Telephone Number: 0049-1715605732
EU Representative eMail address: info.m@luxuslw.de

declare that the DoC is issued under our sole responsibility and belongs to the following product:

Product Name: **Sterile Urethral Catheters for Single Use**
GMDN CODE: 34917
Product Specification: 2.0mm (6 FG/Ch/Fr) ~ 10 mm (30 FG/Ch/Fr)

Of class: IIb
According to MDD 93/42/EEC-Rule 5
Conformity assessment procedure: Directive 93/42/EEC Annex II, Excluding Section 4
Meets the provisions of the directive 93/42/EEC, as amended by directive 2007/47/ EC of European Parlliament and Council of 5 sept 2007 and its transpositions in national laws which apply to it. The declaration is valid in connection with the " final inspection report" of the device

The following harmonised standards and technical specifications have been applied:
Title, Date of standard/specification

No.	*Document number*	*Version number*	*Name of Document*
1.	*ENI5013485*	*2016*	*Quality system—Medical devices-Particular requirements*
2.	*EN ISO14971*	*2019*	*Medical Device-Risk Analysis—Part 1:the Application of risk analysis*
3.	*EN ISO10993-1*	*2020*	*Biological Evaluation of Medical Device-Part 1:Evaluation and testing*
4.	*EN ISO10993-5*	*2009*	*Biological evaluation of medical devices -Part 5:Tests for in vitro cytotoxicity*
5.	*EN ISO 10993-7*	*2008/AC:2009*	*Biological evaluation of medical devices -Part 7:Ethylene oxide sterilization residuals*
6.	*EN ISO10993-10*	*2013*	*Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction*
7.	*EN ISO 15223-1*	*2021*	*Graphic Symbols for use in the labeling of medical device*

8.	EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices -Part 1:Requirements for materials,sterile barrier systems and packaging systems
9.	EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
10.	EN ISO11737-1	2018	Sterilization of medical devices Microbiological methods - Part 1: Determination of a population of microorganisms on products
11.	EN ISO11737-2	2020	Sterilization of medical devices - Microbiological methods -Part 2:Tests of sterility performed in the definition,validation and maintenance of a sterilization process
12.	EN ISO11135	2014/A1:2019	Sterilization of medical health care product -conformation and routine contro requirements
13.	EN ISO 20696	2018	Sterile urethral catheters for single us
14	EN 62366-1	2015	Medical devices - Application of usability engineering to medical devices IEC 62366:2008
15.	EN ISO 20417	2021	Information supplied by the manufacturer of medical devices
16.	EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1:Genera requirements
17.	EN ISO 11138-2	2017	Sterilization of health care products -Biological indicators -Part 2:Biological indicators for ethylene oxide sterilization processes
18.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments -Part 1:Classification of air cleanliness by particle concentration
19.	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments -Part 2:Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
20.	EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7 Connectors for intravascular or hypodermic applications

Registration No.: HD 60146269001
Issue date: 2020-04-13
Expiry date: 2024-05-26

Notified body

:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg

Deutschland

CE0197

Signed for and on behalf of: Nanchang Yili Medical Instrument Co., Ltd

Nanchang	06.03.2020	黄开权
Place of Issue	**Date of Issue**	**Name, function, Signature**