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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din 03 iulie 2023

Solicitantul ANCOTEC-SISTEM SRL, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of 111, MD-2060, tel./fax: 079781169, e-mail achizitii@ancotec.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:

- Autoclav – model **TM-24DV**, producător Jiangyin Binjiang Medical Equipment Co., Ltd, Ţara de origine – China;
- Autoclav – model **TM-35DV**, producător Jiangyin Binjiang Medical Equipment Co., Ltd, Ţara de origine – China

Se anexează următoarele acte:

Declarație de conformitate CE emisă de producător;
Certificat de conformtiate CE valabil pentru dispozitivele fabricate;
Autorizatie producator reprezentant autorizat;
Declarație pe propria răspundere privind veridicitatea datelor prezentate.

Digitally signed by Matei Andrei
Date: 2023.07.03 14:23:21 EEST
Reason: MoldSign Signature
Location: Moldova

Data 03.07.2023 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	

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **ANCOTEC-SISTEM SRL**, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of. 111, MD-2060, 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 dispozitivului medical:

- Autoclav – model **TM-24DV**, producător Jiangyin Binjiang Medical Equipment Co., Ltd, Ţara de origine – China;
- Autoclav – model **TM-35DV**, producător Jiangyin Binjiang Medical Equipment Co., Ltd, Ţara de origine – China

Sunt autentice și corespund realității.

Andrei MATEI *Semnătura* _____
Administrator ANCOTEC-SISTEM SRL *Data 03.07.2023*

Digitally signed by Matei Andrei
Date: 2023.07.03 14:24:21 EEST
Reason: MoldSign Signature
Location: Moldova

JIBIMED

江阴滨江医疗设备有限公司
JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD
江苏省江阴市长寿镇云顾路38号
No.38,Yungu Road, Changshou Twon, Jiangyin City
电话（Tel）：0510-86296768 86270699
传真（Fax）：0510-86270599
邮编（Post-code）：214424

MANUFACTURER'S AUTHORISATION

Date: 28th of JUN 2023

To: ***Medicines and Medical Devices Agency***

WHEREAS

We **JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD.** address No.38,Yungu Road, Changshou Twon, Jiangyin City, China. hereby authorize, do authorize **ANCOTEC-SISTEM SRL** with business office at 44 Cuza-Voda str., Chisinau MD-2060, Republic of Moldova as our local authorized representative to submit the registration file to the Medicines and Medical Devices Agency and to register the following products in the State Register of Medical Devices, as follows:

- Table top pulse vacuum steam sterilizer - model TM-24DV, manufacturer **JIANGYIN BINJIANG MEDICAI EQUIPMENT CO.,LTD. Country of origin - China;**
- Table top pulse vacuum steam sterilizer - model TM-35DV, manufacturer **JIANGYIN BINJIANG MEDICAI EQUIPMENT CO.,LTD. Country of origin - China.**

江阴滨江医疗设备有限公司
JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD

Signed:
Name: Zha Shihong
Title: General Manager
Date: 28th of JUN 2023
Place: Jiangyin

Digitally signed by Matei Andrei
Date: 2023.07.03 14:26:37 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Jiangyin Binjiang Medical Equipment Co., Ltd.
Company Address	: No.38, Yungu Road, Changshou, Zhouzhuang Town, Jiangyin City, Wuxi City, Jiangsu Province, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Desktop Pulsating Vacuum Steam Sterilizer - Class IIb
Models	: TM-20DV, TM-24DV, TM-35DV, TM-50DV
GMDN	: 38671
Certificate Number	: M.2020.106.13500
Report Number	: MD.3925.IB
Initial Assessment Date	: 17.07.2019
Registration Date	: 09.04.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

Declaration of Conformity

For the following products:

Portable Pressure Steam Sterilizer

(Product Name)

TM-24DV TM-35DV

(Model Designation)

GMDN code: 38671 Steam sterilizer

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC) as well as the standards and the directives list as below,

1 EN ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

2 EN 13060:2014 Small steam sterilizers;

3 EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements;

4 IEC 61010-2-040:2015 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials;

5 EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use-EMC requirements, Part1: General requirements;

6 EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements;

7 EN 1041: 2008 / A1: 2013 Information supplied by the manufacturer of medical devices

8 EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

9 EN 62304:2006/AC: 2015Medical device software-Software life-cycle processes

10 EN 62366:2008 Medical devices -Application of usability engineering to medical devices;

11 EN 60601-1-6:2010 + A1:2015 Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability

12 Directive LVD , directive ROHS

Conformity Assessment Route:

Annex II excl. section 4 of Medical Device Directive

CE Marking start date: Oct/01, 2019

Notified Body:

Name: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi Sanayi ve Ticaret Limited Sirketi

Address: Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA Ankara

CE identifier: 2292

The following representative in Europe is responsible for making this declaration:
Name: Llins Service & Consulting GmbH
Address: Am Heiligenhaus 7, 69126, Heidelberg, Germany

The following manufacturer is responsible for making this declaration:
Company Name: Jiangyin Binjiang Medical Equipment Co., Ltd.
Company Address: No 38, Yungu Road, Changshou, Zhouzhuang Town, Jiangyin City, Wuxi City, Jiangsu Province, China

Zha Shihong	GM	2022-07-16
(Signature)	(Position/title)	(Date)

江阴滨江医疗设备有限公司
JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD.

Certificate of Registration

nqa.

兹证明

江阴滨江医疗设备有限公司

统一社会信用代码：91320281250373395 3

经营地址：江苏省无锡市江阴市周庄镇长寿云顾路 38 号

注册地址：江阴市周庄镇长寿云顾路 38 号

的质量管理体系适用于

蒸汽灭菌器的设计、制造和销售（资质许可范围内）

已经 NQA 根据标准

ISO 13485:2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询
SNQA 查询网站：www.snqa.com.cn

总经理

证书号：**131384**

初次发证日期：2022 年 08 月 02 日
证书有效期至：2025 年 08 月 02 日

UKAS MANAGEMENT SYSTEMS
0015

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

使用 UKAS 认可标志表明对 NQA 所持有的编号为 015 的认可证书所涵盖的活动进行认可；
NQA 是 NQA 认证有限公司的商业名称，注册号为 09351758。 注册地址：Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, 英国；
证书为 NQA 所有，客户需在 NQA 要求时将证书返还；
上海恩可埃认证有限公司，地址：中国（上海）自由贸易试验区陆家嘴环路 958 号 2201 室。

Certificate of Registration

This is to certify that the Quality Management System of

Jiangyin Binjiang Medical Equipment Co., Ltd.

Unified Social Credit Code: 913202812503733953

Operation Address: No.38, Yungu Road, Changshou, Zhouzhuang Town, Jiangyin City, Wuxi City, Jiangsu Province, China

Registered Address: No.38, Yungu Road, Changshou, Zhouzhuang Town, Jiangyin City, Jiangsu Province, China

applicable to

Design, manufacture and sale of steam sterilizers (within the scope of qualification license)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **131384**

Issue Date: 02 August 2022

Valid Until: 02 August 2025

UKAS MANAGEMENT SYSTEMS

0015