

No.: ICR Polska/DR/HS221134

Applicant:	JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD
address:	NO.38, YUNGU ROAD, CHANGSHOU TOWN, JIANGYIN CITY, CHINA
Manufacturer:	JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD NO.38, YUNGU ROAD, CHANGSHOU TOWN, JIANGYIN CITY, CHINA
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation (EU) 2017/745 Annexes II & III
Product:	Autoclave
Model(s):	see page 2/2
Product trademark:	n/a
Declared classification:	Class I (Not Sterile according to the Manufacturer's declaration – does not require the participation of a NB)
Technical Documentation:	SF-01TCF prepared by JIANGYIN BINJIANG MEDICAL EQUIPMENT CO.,LTD
Date of review:	23.11.2022
Expiration date	22.11.2027

Review output:

- This document was issued voluntarily and at the request of the applicant.
- The above-mentioned Technical Documentation provided to us by the applicant is compatible in terms of the general requirements for the documentation of this type of product, but its scope of review is not equivalent to Notified Body assessment and such shall be carried independently.
- The manufacturer is responsible for the CE marking process and is not exempt from carrying out all necessary activities related to the legal compliance.



ICR Polska Co. Ltd.
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Director: Rafał Kalinowski



No.: ICR Polska/DR/HS221134

Product: Autoclave

Model(s): YX-12LM, YX-18LM, YX-24LM, YX-18LD, YX-24LD, YX-18LDJ, YX-24LDJ, YX-18LDD, YX-24LDD, YX-12HM, YX-18HM, YX-24HM, YX-18HD, YX-24HD, YX-18HDJ, YX-24HDJ, YX-18HDD, YX-24HDD

LS-35LJ, LS-50LJ, LS-75LJ, LS-100LJ, LS-120LJ, LS-150LJ, LS-35LD, LS-50LD, LS-75LD, LS-100LD, LS-120LD, LS-150LD, LS-35HJ, LS-50HJ, LS-75HJ, LS-100HJ, LS-28HD, LS-35HD, LS-50HD, LS-75HD, LS-100HD, LS-35HG, LS-50HG, LS-75HG, LS-100HG, LS-35HV, LS-50HV, LS-75HV, LS-100HV, LS-60SV, LS-80SV, LS-100SV, LS-120SV

TM-T24J, TM-T24D, TM-XB20J, TM-XB24J, TM-XB20D, TM-XB24D, TM-XD35J, TM-XD50J, TM-XD20D, TM-XD24D, TM-XD35D, TM-XD50D

WS-500YDA, WS-500YDB, WS-500YDC, WS-500YDD, WS-400YDA, WS-400YDB, WS-400YDC, WS-400YDD, WS-280YDA, WS-280YDB, WS-280YDC, WS-280YDD, WS-200YDA, WS-200YDB, WS-200YDC, WS-200YDD, WS-150YDA, WS-150YDB, WS-150YDC, WS-150YDD, WS-90YDB, WS-100YV, WS-150YV, WS-200YV, WS-300YV,

WG-0.25JDF, WG-0.25JSF, WG-0.36JDF, WG-0.36JSF, WG-0.6JDF, WG-0.6JSF, WG-0.25JD, WG-0.25JS, WG-0.36JD, WG-0.36JS, WG-0.6JD, WG-0.6JS, WG-0.8JD, WG-0.8JS, WG-1.0JD, WG-1.0JS, WG-1.2JD, WG-1.2JS, WG-1.5JD, WG-1.5JS, WG-1.5PD, WG-1.5PS, WG-2.0JS, WG-2.0JD, WG-2.0PD, WG-2.0PS, WG-2.5JS, WG-2.5JD, WG-2.5PD, WG-2.5PS

Review output:

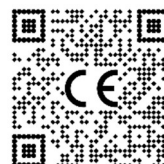
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A handwritten signature in blue ink, appearing to read "Rafał Kalinowski".

Director: Rafał Kalinowski





兹证明

江阴滨江医疗设备有限公司

统一社会信用代码: 913202812503733953

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

L.N. Sh

总经理

证书号: 131384

初次发证日期: 2022年08月02日

本次发证日期: 2025年07月15日

证书有效期至: 2028年08月02日



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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。



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**

Reissue Date: **15 July 2025**

Valid Until: **02 August 2028**



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