



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd

Address: 4th Floor, D5&2nd Floor, D3& 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, JiangSu, CN 214174.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Specification: TC1002 (1 Test/Kit; 20 Tests/Kit; 50 Tests/Kit)

Classification: Others (IVDD)

Conformity Assessment

Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN 13612:2002+AC:2002

EN ISO 23640:2015

EN 13641:2002

Signature:

Name/ Position: Zhitu Zhou / GM

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Date: 9th November, 2020

Place Wuxi, Jiangsu / China



Authorized Signature



POSI CERTIFICATE

This is to certify that the Quality Management System of

BioTeke Corporation (Wuxi) Co., Ltd

Business License Number: 913202065617502076

Registered Address: 1719-5, fourth floor, area A, 1719-3, area B, second floor,
1719-16, first floor, second floor, Huishan Avenue, Huishan Economic
Development Zone, Wuxi, Jiangsu, China

Audit Address: 1719-5, fourth floor, area A (Office), 1719-3, area B, second
floor, 1719-16, first floor, second floor (Production address), Huishan Avenue,
Huishan Economic Development Zone, Wuxi, Jiangsu, China

applicable to

R&D, production and sales of Fluorescence quantitative PCR
instruments, novel coronavirus (SARS-CoV-2) nucleic acid detection
kit (fluorescence PCR method), novel coronavirus antigen detection
kit (colloidal gold method) (export only)

has been assessed and registered by POSI against the provisions of

ISO13485:2016

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

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



[Signature]
General Manager

Certificate Registration No: 381210054R1M

Initial issue date: 2021.04.25

Issue date: 2021.04.25

Valid until: 2024.04.24

Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai, China. Email: info@posicert.com



POSI

Attachment:

Address: 1719-3, area B, second floor, Huishan Avenue, Huishan Economic Development Zone, Wuxi, Jiangsu, China

Scope: R&D ,production of novel coronavirus (SARS-CoV-2) nucleic acid detection kit (fluorescence PCR method)

Address: 1719-3, area B, second floor, 1719-16 , first floor, Huishan Avenue, Huishan Economic Development Zone, Wuxi, Jiangsu, China

Scope: R&D ,production of novel coronavirus antigen detection kit (colloidal gold method)

Address: 1719-16 , second floor, Huishan Avenue, Huishan Economic Development Zone, Wuxi, Jiangsu, China

Scope: R&D ,production of Fluorescence quantitative PCR instruments



Handwritten signature
General Manager



Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

POSI

CERTIFICATE

质量管理体系认证证书

兹证明

无锡百泰克生物技术有限公司

统一社会信用代码：913202065617502076

注册地址：无锡惠山经济开发区惠山大道1719-5号四层A区、1719-3号B区二层、1719-16号一层二层

经营地址：江苏省无锡惠山经济开发区惠山大道1719-5号四层A区（办公）、

1719-3号B区二层、1719-16号一层二层（生产）

的质量管理体系适用于：

荧光定量PCR仪，新型冠状病毒（SARS-CoV-2）核酸检测试剂盒（荧光PCR法），
新型冠状病毒抗原检测试剂盒（胶体金法）的研发，生产和销售（仅限出口）

已经通过上海波西认证有限公司根据标准：

ISO13485:2016

审核和注册

本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POSI进行监督。

查询网站：www.posicert.com

该证书信息可在国家认证认可监督管理委员会官方网站<http://cx.cnca.cn>查询。



总经理

证书编号：381210054R1M

首次发证日期：2021.04.25

本次发证日期：2021.04.25

有效期：2024.04.24



上海波西认证有限公司

上海市浦东新区世纪大道1500号1301-C-7室 Email: info@posicert.com

POSI

附件:

地址: 江苏省无锡惠山经济开发区惠山大道1719-3号B区二层

所对应范围: 新型冠状病毒(SARS-CoV-2)核酸检测试剂盒(荧光PCR法)的研发和生产

地址: 江苏省无锡惠山经济开发区惠山大道1719-3号B区二层、1719-16号一层

所对应范围: 新型冠状病毒抗原检测试剂盒(胶体金法)的研发和生产

地址: 江苏省无锡惠山经济开发区惠山大道1719-16号二层

所对应范围: 荧光定量PCR仪的研发和生产




总经理



上海波西认证有限公司

上海市浦东新区世纪大道1500号1301-C-7室 Email: info@posicert.com