

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **BioTeke Corporation(wuxi) Co.,Ltd**
4th Floor,D5&2nd Floor,D3&
1st and 2nd Floor,D16,
No.1719, Huishan Avenue,
Wuxi
Jiangsu
214174
China

无锡百泰克生物技术有限公司
China
Jiangsu
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
邮编：214174

Holds Certificate No: **MD 750937**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design,Distribution and service of Automated Nucleic Acid Extraction System , Nucleic Acid Extraction Kits, Disposable virus sampling Swab kits,Disposable sterile sampling swab,Colloidal Gold test kits,Immunoassay Test Kits , Fluorescence PCR test kits and PCR in-vitro diagnostic instrument.

核酸全自动提取系统、核酸提取试剂盒、一次性使用病毒采样管、一次性无菌采样拭子、胶体金检测试剂盒、免疫分析试检测试剂盒、荧光PCR检测试剂盒、荧光PCR体外检测设备的设计开发、销售和服务。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-11-25

Latest Revision Date: 2021-11-25

Effective Date: 2021-11-25

Expiry Date: 2024-11-24

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Certificate No: **MD 750937**

Location	Registered Activities
BioTeke Corporation(wuxi)Co., Ltd 4th Floor,D5&2nd Floor,D3& 1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi Jiangsu 214174 China 无锡百泰克生物技术有限公司 中国 江苏省 无锡 惠山经济开发区 惠山大道1719-5号四层A区 邮编: 214174	Design,Distribution and service of Automated Nucleic Acid Extraction System , Nucleic Acid Extraction Kits, Disposable virus sampling Swab kits,Disposable sterile sampling swab,Colloidal Gold test kits,Immunoassay Test Kits , Fluorescence PCR test kits and PCR in-vitro diagnostic instrument. 核酸全自动提取系统、核酸提取试剂盒、一次性使用病毒采样管、一次性无菌采样拭子、胶体金检测试剂盒、免疫分析试剂盒、荧光PCR检测试剂盒、荧光PCR体外检测设备的设计开发、销售和服务。
BioTeke Corporation(wuxi)Co.,Ltd 2nd Floor, D3 No.1719,Huishan Avenue Wuxi City China 无锡百泰克生物技术有限公司 中国 无锡 惠山经济开发区 惠山大道1719-3号B区二层	Manufacture of Nucleic Acid Extraction kits. 生产核酸提取试剂盒。
BioTeke Corporation(wuxi)Co.,Ltd 1st and 2nd Floor D16,No.1719,Huishan Avenue WuXi Jiangsu 214174 China 无锡百泰克生物技术有限公司 中国 江苏省 无锡 惠山经济开发区 惠山大道1719-16号一层二层 邮编: 214174	Manufacture of Automated Nucleic Acid Extraction System <(>,<)> PCR in-vitro diagnostic instrument and Disposable virus sampling Swab kits. 生产核酸全自动提取系统, 荧光PCR体外检测设备, 一次性使用病毒采样管。

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

Certificate No: **MD 750937**

Location

BioTeke Corporation(wuxi)Co.,Ltd
No. 330, Qiyang South Road,
Jiangyin Qingyang
Jiangsu
214401
China
无锡百泰克生物技术有限公司
中国
江苏省
江阴市青阳镇
旌阳南路330号
邮编: 214401

Registered Activities

Manufacture of Colloidal Gold test kits ,Immunoassay Test Kits, Fluorescence PCR test kits, and Disposable sterile sampling swab.
生产胶体金检测试剂盒、免疫分析检测试剂盒、荧光PCR检测试剂盒、一次性无菌采样拭子。



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