

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Zhejiang QL Biotech Co., Ltd.  
Room 501, Building 1#,  
178# Chuangye Rd,  
Qingshanhu, Sub-district, Lin'an District  
Hangzhou  
Zhejiang  
311121  
China


浙江青黎生物技术有限公司  
中国  
浙江省  
杭州市  
临安区青山湖街道  
创业街178号  
1幢501室  
邮编: 311121

Holds Certificate No: **MD 738428**

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

Design and Development, Production and Distribution of In Vitro Diagnostic Kit for the Detection of Hormone, Drug of Abuse, Infectious Disease, Tumour Marker and Cardiac Marker.  
用于检测激素, 滥用药物, 传染病, 肿瘤标志物和心脏标志物的体外诊断试剂盒的设计, 开发, 生产和分销。

For and on behalf of BSI:

  
**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2021-08-31

Latest Revision Date: 2023-03-27

Effective Date: 2021-08-31

Expiry Date: 2024-08-30

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 738428**

Location

Hangzhou Funworld Biotech Co., Ltd.  
3# Floor, Building 1#,  
136 Zhiyi Rd, Yuhang Sub-district,  
Hangzhou  
Zhejiang  
311121  
China  
杭州方沃生物科技有限公司  
中国  
浙江省  
杭州市  
余杭区余杭街道智溢路136号  
1号楼3楼  
邮编: 311121

Registered Activities

Distribution of In Vitro Diagnostic Kit for the Detection of Hormone, Drug of Abuse, Infectious Disease, Tumour Marker and Cardiac Marker.  
用于检测激素, 滥用药物, 传染病, 肿瘤标志物和心脏标志物的体外诊断试剂盒的分销。

Zhejiang QL Biotech Co., Ltd.  
Room 501, Building 1#,  
178# Chuangye Rd,  
Qingshanhu, Sub-district, Lin'an District  
Hangzhou  
Zhejiang  
311121  
China  
浙江青黎生物技术有限公司  
中国  
浙江省  
杭州市  
临安区青山湖街道  
创业街178号  
1幢501室  
邮编: 311121

Design and Development, Production and Distribution of In Vitro Diagnostic Kit for the Detection of Hormone, Drug of Abuse, Infectious Disease, Tumour Marker and Cardiac Marker.

用于检测激素, 滥用药物, 传染病, 肿瘤标志物和心脏标志物的体外诊断试剂盒的设计, 开发, 生产和分销。

Original Registration Date: 2021-08-31

Effective Date: 2021-08-31

Latest Revision Date: 2023-03-27

Expiry Date: 2024-08-30

Page: 2 of 2

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](http://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.