



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Daan Gene Co., Ltd.
No. 19, Xiangshan Road, Science Park
High & New Technology Development
District
Guangzhou
Guangdong
510665
China

广州达安基因股份有限公司
中国
广东省
广州市
高新技术产业开发区
香山路19号
邮编: 510665

Holds Certificate No: **MD 98885**

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

The design, manufacture and sales of reagents for use in nucleic acid and immunological based in vitro diagnostic testing.

基于核酸和免疫的体外诊断试剂的设计、制造和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2006-11-22

Latest Revision Date: 2021-10-29

Effective Date: 2021-11-04

Expiry Date: 2024-11-03

Page: 1 of 2



...making excellence a habit.™

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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 98885**

Location

Registered Activities

Daan Gene Co., Ltd.
No. 19, Xiangshan Road, Science Park
High & New Technology Development District
Guangzhou
Guangdong
510665
China
广州达安基因股份有限公司
中国
广东省
广州市
高新技术产业开发区
香山路19号
邮编: 510665

The manufacture and sales of reagents for use in nucleic acid and immunological based in vitro diagnostic testing.
基于核酸和免疫的体外诊断试剂的制造和销售。

Daan Gene Co., Ltd.
No. 6, Lizhishan Road, Science Park
High & New Technology Development District
Guangzhou
Guangdong
510665
China
广州达安基因股份有限公司
中国
广东省
广州市
高新技术产业开发区
荔枝山路6号
邮编: 510665

The design of reagents for use in nucleic acid and immunological based in vitro diagnostic testing.
基于核酸和免疫的体外诊断试剂的设计。

Original Registration Date: 2006-11-22

Effective Date: 2021-11-04

Latest Revision Date: 2021-10-29

Expiry Date: 2024-11-03

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 or telephone +86 10 8507 3000.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.