

证书编号: 04720Q10103R1M

质量管理体系认证证书

兹证明

北京丹大生物技术有限公司

(统一社会信用代码: 911101120716743951)

住 所: 北京市通州区中关村科技园区通州园光机电一体化产业基地嘉创路 5 号 1 号楼 301-303、310-312 室

生产地址: 北京市通州区中关村科技园区通州园光机电一体化产业基地嘉创路 5 号 1 号楼 301-303、310-312 室

质量管理体系符合:

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖:

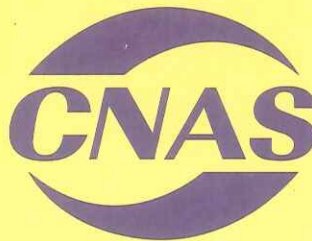
体外诊断试剂(行政许可范围内)的设计开发、生产和服务。

颁证日期: 2020 年 03 月 17 日

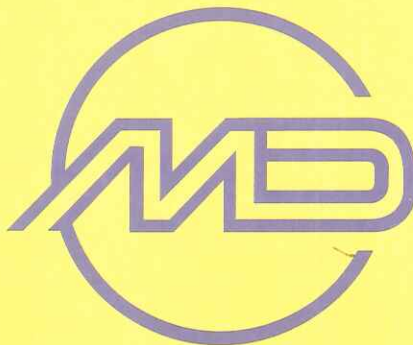
有效期至: 2023 年 03 月 16 日

总经理:

北京国医械华光认证有限公司



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M



REGISTRATION NO. 04720Q10103R1M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Beijing Diagreat Biotechnology Co., Ltd.

Registered Address: Room 301-303, 310-312 Building Xinhualian Science, 5 Jiachuang Road
Zhongguancun Science Park, Tongzhou, Beijing, China

Manufacturing Address: Room 301-303, 310-312 Building Xinhualian Science, 5 Jiachuang
Road Zhongguancun Science Park, Tongzhou, Beijing, China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

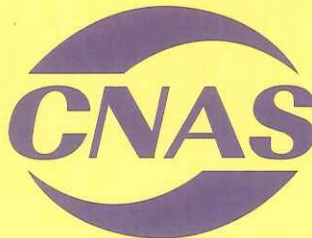
Design, Development, Production and Service of in vitro diagnostic reagents
(products within the scope of administrative licensing).

Date of issue: March 17, 2020

Date of expiry: March 16, 2023

General Manager:

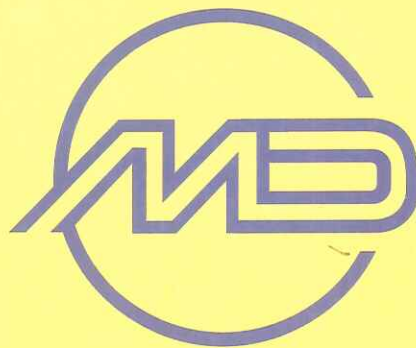
**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



中国认可
国际互认
管理体系

MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



证书编号: 04720Q10000118

医疗器械 质量管理体系认证证书

兹证明

北京丹大生物技术有限公司

(统一社会信用代码: 911101120716743951)

住 所: 北京市通州区中关村科技园区通州园光机电一体化产业基地嘉创路 5 号 1 号楼 301-303、310-312 室

生产地址: 北京市通州区中关村科技园区通州园光机电一体化产业基地嘉创路 5 号 1 号楼 301-303、310-312 室

质量管理体系符合:

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖:

体外诊断试剂(行政许可范围内)的设计开发、生产和服务。

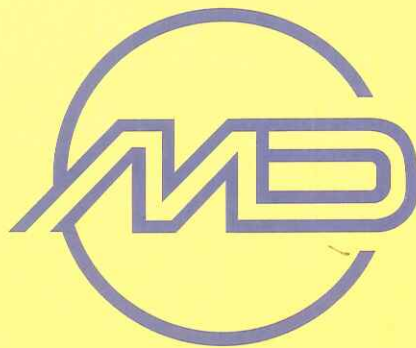
颁证日期: 2020 年 03 月 17 日

有效期至: 2023 年 03 月 16 日

总经理:

北京国医械华光认证有限公司





REGISTRATION NO. 04720Q10000118

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Beijing Diagreat Biotechnology Co., Ltd.

Registered Address: Room 301-303, 310-312 Building Xinhualian Science, 5 Jiachuang Road
Zhongguancun Science Park, Tongzhou, Beijing, China

Manufacturing Address: Room 301-303, 310-312 Building Xinhualian Science, 5 Jiachuang
Road Zhongguancun Science Park, Tongzhou, Beijing, China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Design, Development, Production and Service of in vitro diagnostic reagents
(products within the scope of administrative licensing).

Date of issue: March 17, 2020

Date of expiry: March 16, 2023

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

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