

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Biobase Biodustry(Shandong) Co., Ltd.
Mingshui Economic Development Zone
Zhangqiu District, Jinan City(Biobase
Industrial Park in a
intersection of East Jingshi Road and
Mingbu Road)
Shandong
250200
China

山东博科生物产业有限公司
9137018179889855X7
中国
山东省
济南市
章丘区明水经济开发区
经十东路与明埠路交界山东博科产业园
邮编: 250200

Holds Certificate No: **MD 767775**

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

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-07-14

Latest Revision Date: 2024-07-03

Effective Date: 2022-07-14

Expiry Date: 2025-07-13

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...making excellence a habit.™

Certificate No: **MD 767775**

Registered Scope:

The design, development, manufacture and distribution of IVD kits, calibrators and controls for Clinical Chemistry and Immunochemistry, reagents for Hematology Analyzer. The design, development, manufacture, distribution, installation and provision of maintenance services of Biological Safety Cabinet, Automatic ELISA Processor, Automatic Chemistry Analyzer, Nucleic Acid Extraction System, Automatic Nucleic Acid Extraction System, Electrolyte Analyzer, Auto Hematology Analyzer, Medical Centrifuge, Elisa Microplate Reader.

临床化学和免疫化学的体外诊断试剂盒、校准品和质控品，血细胞分析仪配套试剂的设计、开发、生产和销售。生物安全柜、全自动酶免工作站、全自动生化分析仪、核酸提取仪/全自动核酸提取仪、电解质分析仪、血细胞分析仪、医用离心机、酶联免疫分析仪的设计、开发、生产、销售、安装和售后服务。



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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 767775**

Location

Biobase Biodustry(Shandong) Co., Ltd.
Mingshui Economic Development Zone
Zhangqiu District, Jinan City(Biobase Industrial Park in a
intersection of East Jingshi Road and
Mingbu Road)
Shandong
250200
China
山东博科生物产业有限公司
9137018179889855X7
中国
山东省
济南市
章丘区明水经济开发区
经十东路与明埠路交界山东博科产业园
邮编: 250200

Registered Activities

The design, development, manufacture of IVD kits,
calibrators and controls for Clinical Chemistry and
Immunochemistry, reagents for hematology analyzer.
临床化学和免疫化学的体外诊断试剂盒、校准品和质控品, 血
细胞分析仪配套试剂的设计、开发及生产。

Biobase Biodustry(Shandong) Co., Ltd.
Floor 1, 2 and 5, Building 6, BIOBASE
International Life Science Innovation
Center, North 100 meters from
the intersection of Chunhui Road and
North Gongye Road on the east
Guodian, Licheng, Jinan City
Shandong
250101
China
山东博科生物产业有限公司
9137018179889855X7
中国
山东省
济南市历城区郭店街道
春晖路与工业北路
交叉口北100米路东
博科国际生命科学创新中心6号楼(1层、2层、5层)
邮编: 250101

The design, development, manufacture, distribution,
installation and provision of maintenance services of
Biological Safety Cabinet, Automatic ELISA Processor,
Automatic Chemistry Analyzer, Nucleic Acid Extraction
System, Automatic Nucleic Acid Extraction System, Electrolyte
Analyzer, Auto Hematology Analyzer, Medical Centrifuge, Elisa
Microplate Reader.
生物安全柜、全自动酶免工作站、全自动生化分析仪、核酸提
取仪/全自动核酸提取仪、电解质分析仪、血细胞分析仪、医
用离心机、酶联免疫分析仪的设计、开发、生产、销售、安装
和售后服务。

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Location

Biobase Biodustry(Shandong) Co., Ltd.
North side of plant 1 and east side of
2nd floor in plant 2
Bionew Industrial Park, BIOBASE Road
Ancheng, Pingyin County
Jinan
Shandong
250400
China
山东博科生物产业有限公司
9137018179889855X7
中国
山东省
济南市
平阴县安城镇
博科路智鑫工业园
(1号厂房北侧、2号厂房2层东侧)
邮编: 250400

Registered Activities

The manufacture of Biological Safety Cabinet.
生物安全柜的生产。



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