

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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

Holds Certificate No: **MD 767775**

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

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、血细胞分析仪的设计、开发、生产、销售、安装和售后服务。

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-07-14

Effective Date: 2022-07-14

Latest Revision Date: 2023-07-27

Expiry Date: 2025-07-13



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...making excellence a habit.™

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Location

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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
中国
山东省
济南
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

Biobase Biodustry(Shandong) Co., Ltd.
No.9 Gangxing Road
High-Tech Zone
Jinan City
Shandong
250101
China
山东博科生物产业有限公司
中国
山东省
济南
历城区
港兴路9号
博科集团总部2号楼二、三楼
邮编: 250101

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。

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.
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.

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Location

Biobase Bioindustry(Shandong) Co., Ltd.
Standard Plant No.3,
Jinshui High-end Equipment Manufacturing Industrial Park,
Pingyin County
Jinan
Shandong
250400
China
山东博科生物产业有限公司
中国
山东省
济南市平阴县
锦水高端装备制造产业园
3号标准厂房
邮编: 250400

Registered Activities

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



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