

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: Biobase Biodustry(Shandong), Co., Ltd.  
Intersection Of East Jingshi  
Road and Mingbu Road  
Biobase Industrial Park  
Zhangqiu District ,Jinan  
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

Holds Certificate No: **FM 767776**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 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.

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/全自动核酸提取仪的设计、开发、生产、销售、安装和售后服务。



For and on behalf of BSI:

**Michael Lam - Managing Director Assurance, APAC**

Original Registration Date: 2022-06-21

Effective Date: 2022-06-21

Latest Revision Date: 2022-06-21

Expiry Date: 2025-06-21



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An electronic certificate can be authenticated [online](#).

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Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization. The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate. This certificate is valid only if provided original copies are in complete set.

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Location

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250200  
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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,  
the second and third floors  
of Building 2, and the first floor of Building 3,  
Licheng District  
Jinan  
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、三楼以及3号楼一楼  
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 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.

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/全自动核酸提取仪的设计、开发、生产、销售、安装和售后服务。

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
BSI Management Systems Certificates (Beijing) Co., Ltd.  
Rm. 2008 East Ocean Center, No. 24A Jianguomenwai Street, Beijing 100004, P. R. China Tel: +86 10 8507 3000  
A Member of the BSI Group of Companies.



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Location

Biobase Biodustry(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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