



By Royal Charter

# 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  
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: **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

Latest Revision Date: 2023-07-27

Effective Date: 2022-07-14

Expiry Date: 2025-07-13

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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

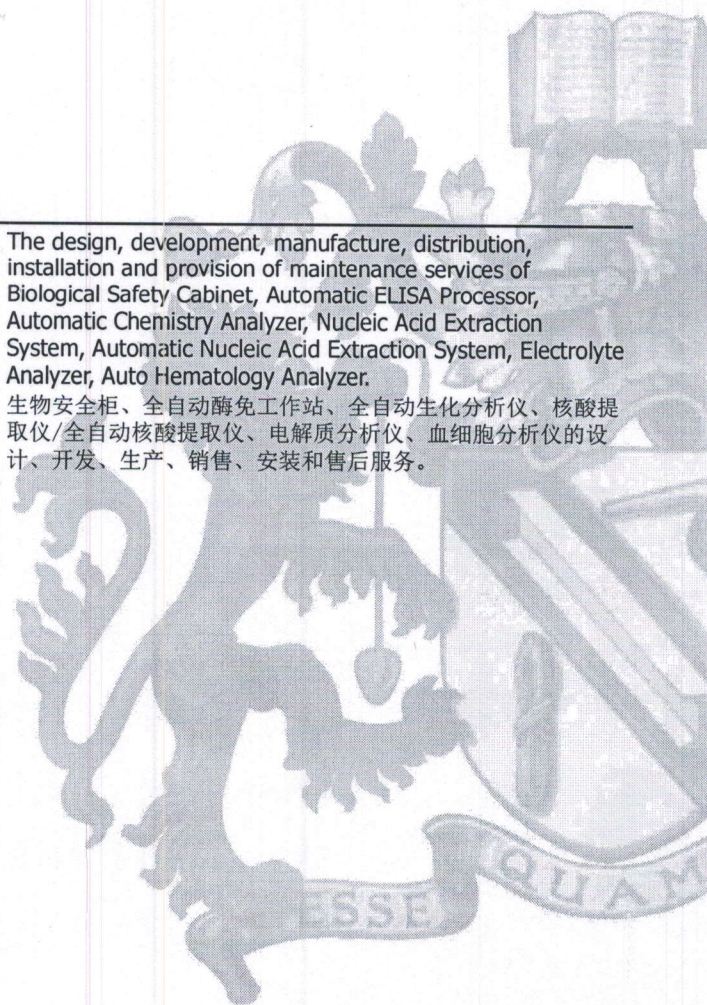
Registered Activities

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  
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

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.  
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

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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Certificate No:

**MD 767775**

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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