

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: **Biobase Biodustry(Shandong) Co., Ltd.**
兹证明 **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**
持有证书

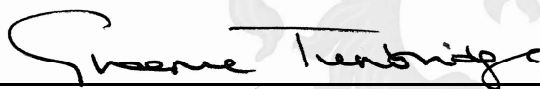
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

并运行符合 ISO 13485:2016 要求的质量管理体系, 认证范围如下:

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 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, Semi-auto Chemistry Analyzer, Auto ESR Analyzer and Microplate Washer.

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, 半自动生化分析仪, 全自动动态血沉分析仪和洗板机的设计开发、生产、销售和售后服务。

For and on behalf of BSI:
BSI代表:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期: 2022-07-14

Effective Date 生效日期: 2025-07-14

Latest Revision Date 最新发证日期: 2025-04-22

Expiry Date 有效期至: 2028-07-13



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The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn)

本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

信息查询及联系方式: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | 电话: + 31 20 3460 780 BSI集团荷兰有限公司, 注册地荷兰, 注册号 33264284 | BSI集团控股有限公司成员

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京 市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 767775**
持有证书:

Location 地点	Registered Activities 认证活动
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	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 and provision of maintenance services of 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, Semi-auto Chemistry Analyzer, Auto ESR Analyzer and Microplate Washer. The design, development, distribution and provision of maintenance services of Biological Safety Cabinet. 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，半自动生化分析仪，全自动动态血沉分析仪和洗板机的设计开发、生产、销售和售后服务。生物安全柜的设计开发、销售和售后服务。

Original Registration Date 首次发证日期: 2022-07-14

Latest Revision Date 最新发证日期: 2025-04-22

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The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
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码33264284 | BSI集团控股有限公司成员
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市
建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

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



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