



兹证明

山东博科生物产业有限公司

统一社会信用代码: 9137018179889855X7

经营地址: 山东省济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园(办公、研发、生产); 山东省济南市工业南路 51 号(生产、销售); 山东省济南市章丘明水经济开发区鑫岳工业园 8#(研发、生产)

注册地址: 山东省济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园

的质量管理体系适用于

体外诊断试剂盒(用于蛋白检测的试剂、用于糖类检测的试剂、用于酶类检测的试剂、用于脂类检测的试剂、用于无机离子类检测的试剂、用于自身抗体检测的试剂、用于其他生理、生化或免疫功能指标检测的试剂)、生物安全柜、医用气溶胶吸附器、压力蒸汽灭菌器、血液冷藏箱、微生物恒温培养箱、全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、全自动生化分析仪、传染病员运送负压隔离舱、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪的研发、生产和销售(资质许可范围内)

已经 NQA 根据标准

ISO 9001:2015

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系,并由 NQA 进行监督。

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。

本证书信息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

SNQA 查询网站: www.snqa.com.cn

Managing Director



015



Certificate Number

45013

Date:

09 July 2018

Reissue Date:

16 November 2020

Valid Until:

09 July 2021

EAC Code:

13/19



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.



This is to certify that the Quality Management System of

Biobase Biodustry (Shandong) Co., Ltd.

Unified Social Credit Code: 9137018179889855X7

Operation Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China (Office, R&D, Production); No. 51, South Gongye Road, Jinan City, Shandong Province, China (Production, Sale); 8# Xinyue Industrial Park, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China (R&D, Production)

Registered Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China

applicable to

R&D, production and sales of in vitro diagnostic kits (reagents for protein detection, reagents for sugar detection, reagents for enzyme detection, reagents for lipid detection, reagents for inorganic ion detection, reagents for autoantibody detection, reagents for the detection of other physiological, biochemical or immunological indicators), biosafety cabinet, air purifier, pressure steam sterilizer, blood bank refrigerator, microbial incubator, automated ELISA processor, diluent for hematology analyzer, hemolysin for hematology analyzer, ELISA microplate washer, laboratory refrigerator, automatic chemistry analyzer, infectious patients transporting negative pressure isolation chamber, automatic chemiluminescence analyzer, nucleic acid extraction instrument and automatic nucleic acid extraction instrument (within the scope of qualification)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

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ISO 13485: 2016

审核和注册

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