

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

ADD: No.51 South Gongye Road, Jinan, China 250100

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E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.mchuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

2014/35/EU Low Voltage Directive and 2014/30/EU Electromagnetic Compatibility Directive have been taken as reference for these processes

Company Name: **Biobase Biodustry(Shandong) Co., Ltd.**
No. 51 South Gongye Road, Jinan, Shandong Province, China

Brand: **BIOBASE**

Related Directives and Annex: **2014/35/EU Low Voltage Directive (LVD)**
2014/30/EU Electromagnetic Compatibility (EMC)

Related Standards: **EN 61326-1:2013; EN 61010-1:2010**

Product(s): **Balance**

Type(s)/Model(s): **See Annex**

Classification: **Laboratory Equipment**

Examination Period: **November 4, 2019**

Date of Expiry: **November 3, 2024**

Review Result: We, Biobase Biodustry(Shandong) Co., Ltd., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Low Voltage Directive 2006/42/EC and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: **2019**

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

General Manager: **Robert Wang**

Document No: **BKSD-191141**



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Annex

Type(s)/Model(s)

BA604C; BA1004C; BA1204C; BA1604C; BA2004C;
BA2204C; BA1003C; BA2003C; BA3003C; BA1004N;
BA1104N; BA1204N; BA2004N; BA2104N; NA2204N;
BA504B; BA604B; BA1004B; BA1104B; BA1204B;
BA1604B; BA2004B; BA2204B; BA2104B; BA2104B;
BP1003B; BP1203B; BP2003B; BP3003B; BP4103B;
BP5003B; BP10003; BP1003P; BP2003P; BP12002;
BP21002; BP31002; BP50002; BP21001; BP31001;
BP41001; BP51001; BP61001; BE1002; BE2002; BE3002;
BE4002; BE5002; BE6002; BE10002; BE20002; BE30002;
BE50002; BE2001; BE4001; BE5001; BE6001; BE8001;
BE10001; BE16001; BE20001; BE30001; BE40001;
BE50001; BE60001; BE80001; BE100001; BE150001;
BE200001; BE300001; BE1000; BE2000; BE3000; BE6000;
BE10000; BE15000; BE20000; BE30000; BE1002G;
BE2002G; BE3002G; BE6002G; BE10002G; BE20002G;
BE30002G; BE40002G; BE50002G; BE60001GF;
BE100001GF; BE150002GF; BE6000GF; BE10000GF;
BE15000GF; BE1002N; BE2002N; BE3002N; BE5002N;
BE6002N; BE10002N; BE3001N; BE6001N; BE10001N;
BE20001NF; BE30001NF; BE50001NF; BM-50-10;
BM-50-5; BM-50-1; BA-100D; BA-200D

Year of DOC marking: 2019

Signed for and on behalf of

Company: Biobase Biodustry(Shandong) Co., Ltd.

General Manager: Robert Wang

Document No: BKSD-191141



Version BKSD2019 LVD & EMC DGC 1.0



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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已经 NQA 根据标准

ISO 13485: 2016

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。

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45014

Date:

09 July 2018

Reissue Date:

16 November 2020

Valid Until:

09 July 2021



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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)

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Certificate of Registration

BP Series Electronic Precision Balance

Functions:

- * Multiple functions including auto-counting, unit conversion (metric carat, gold ounce, etc.), stability, full-scale faring, zero-memory, etc.
- * Built-in RS232C output interface for computer and printer.

Power Supply: AC220V±10%, 50/60Hz; 110V±10%, 50/60Hz, Power Cord, no battery.



Technical Parameters:

Model	Capacity	Readability	Repeatability	Linear Error	Scale Size	Package Size	Gross Weight
BP12002	0~1200g	10mg	10mg	20mg	Φ160mm	480*375*515	8.5kg
BP21002	0~2100g						
BP31002	0~3100g						
BP50002	0~5000g	100mg	100mg	100mg	Φ160mm	480*375*515	8.5kg
BP21001	0~2100g						
BP31001	0~3100g						
BP41001	0~4100g						
BP51001	0~5100g						
BP61001	0~6100g			200mg			

Standard Accessory:

Balance body, scale, clean cloth.

BE Series Electronic Balance

Features:

- * AC/DC exchangeable, balance level, LCD display, rapid weighing response and high stability.
- * Sensor adopts unique locking device, which guarantees protection of balance during transportation.



Scale Size: Φ125mm

Scale Size: 130*130mm

Scale Size: 160*160mm

Scale Size: 255*190mm

Functions:

- * System operations: including auto-counting, percentage, automatic calibration, multi-point calibration, standard weights (optional)
- * Multiple functions guarantee easy and reliable operation, including unit conversion (metric carat, gold ounce, etc.), stability, memory, full-scale faring.
- * Built-in RS232C output interface guarantees direct connection to external equipment such as computer and printer.

Power Supply: AC110/220V±10%, 50/60Hz; Capacity <10kg: Power cord, dry battery reservation position (5#*6pcs), no battery; Capacity ≥10kg: Power cord, accumulator.

Technical Parameters:

Model	Capacity	Readability	Repeatability	Linear Error	Scale Size	G. W.	Package Size			
BE1002	0~100g	0.01g	0.01g	0.02g	Φ125mm	2.3kg	365*265*170mm			
BE2002	0~200g				130*130mm					
BE3002	0~300g									
BE4002	0~400g		0.02g	0.03g	160*160mm					
BE5002	0~500g				Φ125mm					
BE6002	0~600g									
BE10002	0~1000g									
BE20002	0~2000g		0.1g	0.1g	0.1g			130*130mm	4.5kg	460*395*250mm
BE30002	0~3000g							160*160mm		
BE50002	0~5000g									
BE2001	0~200g	Φ125mm								
BE4001	0~400g									
BE5001	0~500g									
BE6001	0~600g	130*130mm								
BE8001	0~800g									
BE10001	0~1000g									
BE16001	0~1600g	160*160mm								
BE20001	0~2000g									
BE30001	0~3000g									
BE40001	0~4000g	0.2g		0.2g	255*190mm	4.5kg	460*395*250mm			
BE50001	0~5000g									
BE60001	0~6000g									
BE80001	0~8000g	1g	1g	1g	130*130mm	2.3kg	365*265*170mm			
BE100001	0~10000g									
BE150001	0~15000g				160*160mm					
BE200001	0~20000g									
BE300001	0~30000g		0.3g	0.3g	255*190mm	4.5kgm	460*395*250mm			
BE1000	0~1000g									
BE2000	0~2000g									
BE3000	0~3000g	1g			130*130mm	2.3kg	365*265*170mm			
BE6000	0~6000g									
BE10000	0~10000g				160*160mm	2.3kg	365*265*170mm			
BE15000	0~15000g									
BE20000	0~20000g				255*190mm	4.5kgm	460*395*250mm			
BE30000	0~30000g									