

BIOBASE

BIOBASE BIODUSTRY (SHANDONG) CO., LTD.
ADD: No 51 South Gongye Road, Jinan, China 250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

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

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

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

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

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

Product(s): **Compound Microscope**

Type(s)/Model(s): **XS-208A, XS-208B, XS-208C, XS-208AP, XS-208BP, XS-208AB**

Classification: **Laboratory Equipment**

Examination Period: **Apr. 25, 2019**

Date of Expiry: **Apr. 24, 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 2014/35/EU 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: 

Document No: **BKSD-1904251**





CERTIFICATE

ATTESTATION CERTIFICATE OF MACHINERY AND ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

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

2006/42/EC Machinery Directive 2014/30/EU Electromagnetic Compatibility Directive
and 2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name : **Jinan Biobase Biotech Co., Ltd.**

Company Address : No.51 South Gongye Road, Jinan, Shandong, China 250101

Related Directives and Annex : **2006/42/EC Machinery Directive**
2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility Directive

Related Standards : **EN ISO 12100:2010, EN 60204-1:2006+A1:2009+AC:2010**
EN 61010-1:2010, EN 61326-1:2013

Product Name : **Low Temperature Freezer**

Report No and Date : TELMJ201810082771

Product Brand/Model/Type : BDF-25H150, BDF-25H200, BDF-25H300, BDF-25H389,
BDF-25H525, BDF-25V259, BDF-25V450, BDF-25V268,
BDF-25V270, BDF-25V328, BDF-40V253, BDF-40V288,
BDF-40V288A, BDF-40V525, BDF-40V450, BDF-40V90,
BDF-40V270, BDF-40V268, BDF-40V328, BDF-40H100,
BDF-40H200, BDF-40H300, BDF-40H390, BDF-40H485,
BDF-60H58, BDF-60H118A, BDF-60H218, BDF-60H318,
BDF-60H458, BDF-86V158, BDF-86V340, BDF-86V936,
BDF-86V100, BDF-86V108, BDF-86V308, BDF-86V528,
BDF-86V540, BDF-86V388, BDF-86V398

Certificate Number : **M.2018.201.N7086**

Initial Assessment Date : 17.10.2018

Registration Date : 18.10.2018

Reissue Date/No : -

Expiry Date : **17.10.2023**

UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udem.com.tr





C E R T I F I C A T E

ATTESTATION CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been observed
2014/30/EU Electromagnetic Compatibility Directive and
2014/35/EU Low Voltage Directives have been taken as references for these processes

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

Company Address : No.2717 Gongyeyi Road,Mingshui Economic Developing Zone,
Zhangqiu,Jinan,Shandong,China

Related Directives and Annex : 2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility Directive

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

Product Name : Incubator

Report No and Date : OUCE-SH-174058

Product Brand/Model/Type : BJPX-C50,BJPX-C80,BJPX-C160,BJPX-C270,BJPX-H30,BJPX-H48II,BJPX-H50,
BJPX-H64II,BJPX-H80,BJPX-H123II,BJPX-H160,BJPX-H230II,BJPX-H270,
BJPX-B80,BJPX-B150,BJPX-B200,BJPX-B250,BJPX-B300,BJPX-B400,BJPX-HT150,
BJPX-HT200,BJPX-HT250,BJPX-HT300,BJPX-HT400,BJPX-M150,BJPX-M200,
BJPX-M250,BJPX-M300,BJPX-M400,BJPX-A250,BJPX-A300,BJPX-A400,
BJPX-A500,BJPX-L150,BJPX-L250,BJPX-L300,BJPX-L400,BJPX-L500,BJPX-G,
BJPX-200BX,BJPX-200CX,BJPX-P10,BJPX-P20,BJPX-103B,BJPX-100B,BJPX-200B,
BJPX-1102,BJPX-2102,BJPX-1102C,BJPX-2102C,BJPX-2012,BJPX-2012R

Certificate Number : M.2016.201.N1827

Initial Assessment Date : 15.08.2017

Registration Date : 16.08.2017

Reissue Date/No : -

Expiry Date : 15.08.2022


UDEM International Certification
Auditing Training Centre Industry
and Trade Co. Ltd.

The validity of the certificate can be checked through www.udemltd.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udemltd.com.tr



Certificate of Compliance



No. 0P171016.JBBTQ23

Technical Construction File no. TJS201710132133

Certificate's
Holder:

Jinan Biobase Biotech Co., Ltd.
Room 501, Tianqiao District Technology Center,
No. 6 Lanxiang Middle Road, Tianqiao District, Jinan

Certification ECM
Mark:



Product:
Model(s):

Centrifuge
(see the following annex I)

Verification to:

Standard:
EN 61326-1:2013, EN 61000-6-1:2007,
EN 61000-6-3:2007+A1:2011+AC:2012,
EN 61010-1:2010,
EN 60204-1:2006+A1:2009+AC:2010

related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** and to perform all the necessary activities, as required by the Directive before placing the **CE** Mark on the product(s).

Date of issue 16 October 2017

Expiry date 15 October 2022

Chief Manager
Marco Morina

Deputy Manager
Amanda Payne



Ente Certificazione Macchine Srl

Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
 ☎ +39 051 6705141 📠 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Annex I

No. 0P171016.JBBTQ23

Technical Construction File no. TJS201710132133



Model(s): Mini-4K, Mini-6K, Mini-7K, Mini-10K, Mini-10K+, Mini-15K, Mini-4610K, Mini-4610KII, Mini-4KH, Mini-6KH, Mini-10KH, LC-HD, LC-4KII, LC-H4KII, LC-4KA, LC-4K-2, LC-5K, LC-4KB, LC-4KC, LC-T4K, LC-H4K, BKC-TL4, BKC-TL4II, BKC-TL4III, BKC-TL4IV, BKC-TL5VII, BKC-TL5III, BKC-TL5IV, BKC-TL5, BKC-TL5II, BKC-TL6, BKC-TL6II, BKC-TL4V, BKC-TL5VI, BKC-TL5V, BKC-TL6III, BKC-TL6IV, BKC-TL6V, BKC-TL5L, BKC-TL5LII, BKC-TL5RIV, BKC-TL6R, BKC-TL8R, BKC-VL5R, BKC-VL6R, BKC-VL8R, BKC-TL5R, BKC-TL5RII, BKC-TL5RIII, BKC-TL5RL, BKC-VL6RLII, BKC-VL6RL, BKC-VL7RL, BKC-VL8RL, BKC-MH16, BKC-TH16, BKC-TH18, BKC-TH16II, BKC-TH18II, BKC-TH21, BKC-TH18R, BKC-TH18RII, BKC-TH23R, BKC-TH16R, BKC-TH20R, BKC-TH16RII, BKC-TH20RII, BKC-TH12R, BKC-TH16RIII, BKC-TH20RIII, BKC-TH24RII, BKC-VH20R, BKC-VH21RII, BKC-TH23RII, BKC-TH24R, BKC-TH24RL, BKC-VH20RII, BKC-VH21RL, BKC-VH10RL, BKC-TH20RL, BKC-TH21RL, BKC-GC12, BKC-GC24, BKC-PCR16, BKC-PRP5, BKC-MF5A, BKC-MF5B, BKC-MF5C, BKC-AU4, BKC-AU5, BKC-AU5R, BKC-BB6, BKC-BB6A, BKC-BB7, BKC-HC12A, BKC-TB12, BKC-TB4K, BKC-OIL5VII



CERTIFICATE

ATTESTATION CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

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

2014/30/EU Electromagnetic Compatibility Directive and

2014/35/EU Low Voltage Directives have been taken as references for these processes

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

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

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

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

Product Name : **Refrigerator**

Report No and Date : TELMJ1903223021

Product Brand/Model/Type : BPR-5V50(G), BPR-5V50(F), BPR-5V70(G), BPR-5V70(F), BPR-5V95(G), BPR-5V95(F), BPR-5V100(G), BPR-5V100(F), BPR-5V130(G), BPR-5V130(F), BPR-5V260, BPR-5V360, BPR-5V650, BPR-5V758, BPR-5V1000, BPR-5V1500, BPR-5V160, BPR-5V250, BPR-5V310, BPR-5V588, BBR-4V120, BBR-4V160, BBR-4V210, BBR-4V250, BBR-4V310, BBR-4V650, BBR-4V1000

Certificate Number : **M.2019.206.C0569**

Initial Assessment Date : 03.04.2019

Registration Date : 04.04.2019

Reissue Date/No : -

Expiry Date : **03.04.2024**

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udem.com.tr


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



BIOBASE

Biobase Biodustry (Shandong) Co., Ltd
ADD: BIOBASE Headquarters, No. 9 Gangxing Road, Pilot Free Trade Zone of Jinan, Shandong, China
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

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

Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU and 2006/42/EC Machinery Directive have been taken as reference for these processes

Company Name: **Biobase Biodustry (Shandong) Co., Ltd**
BIOBASE Headquarters, No. 9 Gangxing
Road, Pilot Free Trade Zone of Jinan, Shandong, China

Related Directives and Annex: **2014/35/EU Low Voltage Directive (LVD)**
2014/30/EU Electromagnetic Compatibility (EMC)
2006/42/EC Machinery Directive(MD)

Related Standards: **EN 61010-1:2010; EN 61326-1:2013**
EN 292-1:1991; EN 292-2:1991; EN 1050:1997

Product(s): **Shaker**

Type(s)/Model(s): **SK-O330-Pro**

Classification: **Laboratory Equipment**

Examination Period: **June 16, 2021**

Date of Expiry: **June 15, 2026**

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 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU and Machinery Directive 2006/42/EC was detected.

Year of DOC marking: **2021**

Signed for and on behalf of

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

RA Specialist: **Zona**

Document No: **BKSD-Z21061601**





Garanzia di Qualità del Processo di Produzione

Quality Assurance of the Production Process

n. ECM PED-D1 2020-CO82

Rilasciato i sensi della Direttiva 2014/68/UE – Allegato III
Issued according to 2014/68/EU Directive – Annex III

Fabbricante

Manufacturer

Ragione Sociale

Company Name

Sede Legale

Registered office

Sede Operativa

Headquarters

Descrizione dell'attrezzatura/insieme

Equipment/assemblies description

Modelli

Models

Fascicolo Tecnico n°

Technical file no.

Dati tecnici

Technical Data

Biobase Disinfection (Shandong) Co., Ltd.

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave

BKM-Series, BKQ-Series, BKS-Series

TPMJ202009043201

V: 1.8 to 352L

PS: -1 to 3bar

Fluid Group: 2

Temperature Range: 0 to 150°C

Questo certificato è basato sul rapporto di verifica ispettiva n. PTPRD01_CO82 emesso il 04/09/2020.

I risultati delle verifiche periodiche del sistema qualità sono parte integrante di questa notifica.

Questo Certificato di Notifica della garanzia di qualità della produzione è valido fino al 06/09/2023 e può essere ritirato se dalle verifiche ispettive di sorveglianza risulta che il sistema di qualità della produzione non è più conforme a quanto previsto dall'allegato III modulo D1.

In accordo con quanto previsto nell'Allegato III modulo D1 della Direttiva 2014/68/UE la marcatura CE sul prodotto deve essere seguita dal n. 1282 che identifica ECM come l'Organismo Notificato incaricato della sorveglianza della produzione.

This certificate is based on the audit report no. PTPRD01_CO82 issued on 04/09/2020.

The results of periodic audits of the quality system is an integral part of this notification.

This Certificate of Notification of production quality assurance is valid until 06/09/2023 and can be withdrawn if surveillance audits show that the quality system of production no longer complies with the provisions in Annex III module D1.

In accordance with the Annex III module D1 of Directive 2014/68/EU the CE marking must be followed by n. 1282 that identifies ECM as Notified Body responsible for supervising the production.

Esempio di marcatura

Marking example



Data di prima emissione

Date of first issue

07/09/2020

☐ Estensione - Extension

☐ Rinnovo - Renewal

Valsamoggia (BO)

Data - Date 07/09/2020

Timbro

Scadenza - Expiry date 06/09/2023



Firma autorizzata

Authorized signature

Amanda Payne
(Deputy Manager)

Questo certificato, compreso l'allegato, può essere riprodotto solo integralmente e senza alcuna variazione. Pagina 1 di 2
This certificate, annex included, may only be reproduced in its entirety and without any change. Page 1 of 2

Ente Certificazione Macchine srl

Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)

+39 0516705141 +39 0516705156 ecm@entecerma.it www.entecerma.it



Allegato al Certificato n. *Appendix to Certificate no.* **n. ECM PED-D1 2020-C082**

Rilasciato i sensi della Direttiva 2014/68/UE – Allegato III
Issued according to 2014/68/EU Directive – Annex III

Richiedente

Applicant

Ragione Sociale

Company Name

Sede Legale

Registered office

Sede Operativa

Headquarters

Apparecchio/insieme

Equipment/assembly

Biobase Disinfection (Shandong) Co., Ltd.

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave

Apparecchio soggetto a sorveglianza

Equipment subjected to surveillance

BKM-Series, BKQ-Series, BKS-Series

Valsamoggia (BO)

Data - Date 07/09/2020

Timbro



Firma autorizzata
Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 06/09/2023

FINE DEL CERTIFICATO – END OF CERTIFICATE

Questo certificato, compreso l'allegato, può essere riprodotto solo integralmente e senza alcuna variazione. Pagina 2 di 2
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Ente Certificazione Macchine srl

Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)

☎ +39 0516705141 📠 +39 0516705156 ✉ ecm@entecerma.it www.entecerma.it



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)

SNQA's website: 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



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



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 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。

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

45014

Date:

09 July 2018

Reissue Date:

16 November 2020

Valid Until:

09 July 2021



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 13485: 2016

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)

SNQA's website: www.snqa.com.cn

Managing Director



015



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