



REGISTRATION NO. 04719Q10781R1M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Jinan Biobase Biotech Co., Ltd.

Registered Address: OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City, Shandong

Manufacturing Address: North Side of Jiwang Road, Mingshui Economic Development District, Zhangqiu, Jinan City; OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City, Shandong

Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of biological safety cabinet; Class I Biosafety Cabinet; carbon dioxide incubator; low temperature freezer; laminar flow cabinet; biological isolation chamber; centrifuge; fume hood; PCR cabinet; dispensing booth.

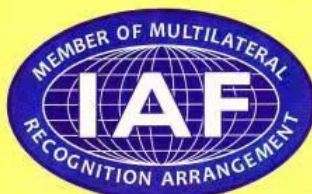
Date of issue: July 22, 2019

Date of expiry: July 21, 2022

Date of change: July 06, 2021

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993

质量管理体系 认证证书

证书号：HXC18921Q20254R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：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）

办公地址：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）

生产/经营地址：山东省济南市工业南路 51 号（生产）/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（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/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（生产）

邮编：250200

质量管理体系符合

GB/T 19001-2016 / ISO 9001:2015 标准条款的要求

该体系认证所覆盖的范围

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
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、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
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证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
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查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

www.hxccc.org

010-57146599

No.0002277

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. : HXC18921Q20254R0M

Awarded to

Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Quality Management System of the above
organization has been assessed and Found to be in accordance with
the requirements of the standard:**

GB/T 19001-2016 / ISO 9001:2015

Scope of this management Certification

**R&D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
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The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802, 2nd Building, No. 6 South Street of Gulou, Changping District, Beijing City, China 010-57146599

No. 0002277



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 inspected 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 : **Jinan Biobase Biotech Co., Ltd.**

Company Address : **No.51, South Gongye Road, Jinan, Shandong
Province, 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 : **Biological Safety Cabinets**

Report No and Date : **OUCE-SH-163282-01-LVD/EMC**

Product Brand/Model/Type : **BSC-1100IIA2-X, BSC-1100IIB2-X, BSC-1200IIA2-Z, BSC-1300IIA2-X,
BSC-1300IIB2-X, BSC-1500IIA2-X, BSC-1500IIB2-X, BSC-1800IIA2-X,
BSC-1800IIB2-X, 11229 BBC 86, 11230 BBC 86, 11231 BBC 86,
11234 BBC 86, 11235 BBC 86, 11236 BBC 86, 11240 BBC 86,
BSC-4FA2, BSC-3FA2, BSC-6FA2, BSC-4FB2, BSC-3FB2, BSC-6FB2**

Certificate Number : **M.2016.201.Y2306**

Initial Assessment Date : **07.12.2016**

Registration Date : **08.12.2016**

Reissue Date/No : **-**


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 Morino



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



Garanzia di Qualità del Processo di Produzione

Quality Assurance of the Production Process

n. ECM PED-D1 2018-DD33

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 BIODUSTY (SHANDONG) CO., LTD.

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

No.2717 Gongyeyi Road, Mingshui Economic Developing Zone, Zhangqiu, Jinan, Shandong, 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

TPMJ201806222564

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_DD33 emesso il 25/06/2018.

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 25/06/2021 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_DD33 issued on 25/06/2018.

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 25/06/2021 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

CE 1282

Data di prima emissione

Date of first issue

26/06/2018

☐ Estensione - Extension

☐ Rinnovo - Renewal

Valsamoggia (BO)

Data - Date 26/06/2018

Timbro



Firma autorizzata

Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 25/06/2021

Questo certificato, compreso l'allegato, può essere riprodotto solo integralmente e senza alcuna variazione. Pagina 1 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



Allegato al Certificato n.

Appendix to Certificate no.

n. ECM PED-D1 2018-DD33

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 BIODUSTRY (SHANDONG) CO., LTD.

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

No.2717 Gongyeyi Road, Mingshui Economic Developing Zone, Zhangqiu, Jinan, Shandong, 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 26/06/2018

Timbro



Firma autorizzata

Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 25/06/2021

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

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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 : JINAN BIOBASE MEDICAL CO., LTD.

Company Address : NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, 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 : Centrifuge

Report No and Date : EC.BIOBASE.20210727001-R-1

Product Brand/Model/Type : See Annex Page

Certificate Number : M.2021.206.C66658

Initial Assessment Date : 02.08.2021

Registration Date : 03.08.2021

Reissue Date/No : -

Expiry Date : 02.08.2026


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Auditing Training Centre Industry
and Trade Inc. Co.

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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





CERTIFICATE

ANNEX of Certificate No: M.2021.206.C66658

Product Brand/Model/Type : BKC-VL8RL-B, BKC-VL6RL-B, BKC-VL6RL-BI, BKC-VL5RL-B, BKC-VL6RCL, BKC-VL5RMCL, BKC-VH10RL-B, BKC-TL5RL-B, BKC-TL5RCL, BKC-TL5RMCL, BKC-TH21RL-B, BKC-VL6L-B, BKC-VL6L-BI, BKC-VL6L-BII, BKC-VL6KCL, BKC-VL5KL, BKC-VL5KCL, BKC-TL5RM, BKC-TL5RM-I, BKC-TL5RM-IC, BKC-TL6RM, BKC-TL4M, BKC-TL5M, BKC-TL5M-I, BKC-TL5M-II, BKC-TL6M, BKC-TL5M-IC, BKC-TL5MC, BKC-TL5M-IIC, BKC-TL4G, BKC-TL5G, BKC-TLCT4Y, BKC-TLCT5Y, BKC-TL4X, BKC-TH21RM, BKC-TH25RM, BKC-TH16RM, BKC-TH18RM, BKC-TH20RM, BKC-TH26RM, BKC-MH12-B, BKC-MH16-B, BKC-MH16-BI, BKC-MH18-B, BKC-MH20-B, BKC-TL4C, BKC-TL5E, BKC-TL6K, BKC-TL6A, BKC-TL6E, BKC-TL5EC, BKC-TL4A, BKC-TL5ER, BKC-TL7RML, BKC-TL6BL, BKC-TH10RA, BKC-TH12R-B, BKC-TH10R-B, BKC-TH21RMC, BKC-TH21R-B, BKC-TH21RM-B, BKC-TL5REC, BKC-TH28M, BKC-TH12, BKC-TH16E, BKC-TH16WC, BKC-TH18I, BKC-TH18WC, BKC-TH18IC, BKC-TH21WC, BKC-TH16RE, BKC-TH20R-B, BKC-TH16R-B, BKC-TH21RWC, BKC-TH18RMC, BKC-TH18RWC, BKC-TH18RW, BKC-TH16RMC, BKC-TCT1, BKC-TCT2, Mini-7, Mini-12, Mini-4, Mini-5, BKC-AU5MT, BKC-AU5KT, BKC-AU5BT, BKC-AUV5ML, BKC-AUV5BL, BKC-AUV5TL, BKC-AUV5KL, BKC-AUV5RL, BKC-AUV5RKL, BKC-AU5ML, BKC-AU5KL, BKC-AU5AL, BKC-TL5PI, BKC-TL5P, BKC-TL6RMCL, BKC-TL6RMBL, BKC-T7RMC, BKC-L6K, BKC-OIL4P, BKC-TL5RRL, DDL-8R, DDL-6R, DGL-10R, TDL-5R, TGL-21R, DD-6R, DD-6R-I, DD-6R-II, TDL-5M, TDL-5M-I, TD-4M, TD-5M, TD-5M-I, TD-5M-II, TD-6M, TD-4G, TD-4Y, TD-4X, TD-5G, TGL-21M, TGL-25M, TGL-16M, TGL-18M, TGL-20M, TGL-26M, TG-12W, TG-16W, TG-16W-I, TG-18W, TG-20W, TD-4C, TD-5E, TDL-5E, CDL-7M, TD-6K, TD-6A, TD-6B, TD-6E, GL-10A, GL-12K, G-12K, TGL-16E, TG-16E, Cytoprep-1, Cytoprep-2, Mini-7, Mini-12, TGL-20K, TGL-16K, TG-18I, DDL-5R, DDL-6R-I, TD-5MT, DD-5MT, DDL-5RT, TDL-5MT, TD-5Y, TD-5R, GL-28M, TD-5EC, DL-5EC, TDL-5RC, TD-5M-IC, TDL-5M-IC, TD-5MC, GL-10K, TD-4A, Mini-4, Mini-5, TD-5P-I, TD-5P, GL-21MC, GL-21M, TD-5M-IIC, DL-6MC, DL-6MB, CDL-7MC, DD-6K, DD-6KC, TD-4P, TDL-5MC, TGL-21MC, TG-21WC, TGL-18MC, GL-21K, TG-18WC, TGL-16MC, TG-16WC, TGL-18WC, TGL-18W, TG-18IC, TDL-5AT, TD-5BT, TDL-5KT, DD-5KT, DD-5BT, DDL-5KT, DD-5IT, TDL-6M, , DD-5K, DD-5KC, DDL-6RC, DDL-5MC


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

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

