



# 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**

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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](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)

  
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# 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 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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# 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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# 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

CE 1282

Data di prima emissione

Date of first issue

07/09/2020

☐ Estensione - Extension

☐ Rinnovo - Renewal

Valsamoggia (BO)

Data - Date 07/09/2020

Timbro



Firma autorizzata

Authorized signature

Amanda Payne  
(Deputy Manager)

Scadenza - Expiry date 06/09/2023

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 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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# 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 Biotech Co., Ltd.

Company Address : Room 501, Tianqiao District Technology Center, No.6 Lanxiang  
Middle Road, Tianqiao District, Jinan, China

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

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

Product Name : Drying Oven

Report No and Date : 201709252104-LVD/EMC

Product Brand/Model/Type : BOV-T30C/BOV-T70C/BOV-T140C/BOV-T270C/BOV-T25F/BOV-T50F/  
BOV-T105F/BOV-T200F/BOV-V30F/BOV-V35F/BOV-V45F/BOV-V65F/  
BOV-V70F/BOV-V125F/BOV-V136F/BOV-V225F/BOV-V230F/  
BOV-V429F/BOV-V625F/BOV-V640F/BOV-V960F/BOV-V27F/  
BOV-V90F/BOV-V135F/BOV-V216F/BOV-XF124/BOV-30V/BOV-50V/  
BOV-90V/BOV-215V/BOV-90VL/BOV-215VL/BOV-D30/BOV-D50/BOV-D70/  
BOV-D140/BOV-D240/BOV-H50F/BOV-H90F/BOV-H125F/BOV-H216F

Certificate Number : M.2017.201.N2107

Initial Assessment Date : 27.09.2017

Registration Date : 28.09.2017

Reissue Date/No : -

Expiry Date : 27.09.2022

  
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# 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**

  
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# C E R T I F I C A T E

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

Company Name : Biobase Biodystry (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 : -

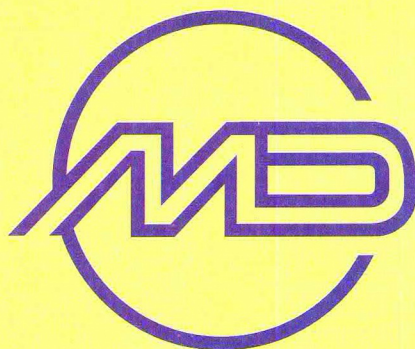
Expiry Date : 15.08.2022

  
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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:** Floor 5, Science and Technology Incubator Building, No. 6  
Lanxiangzhong Road, Tianqiao District, Jinan City

**Postcode:** 250000

**Manufacturing Address:** No. 51 South Gongye Road, Jinan City; North Side of  
Jiwang Road, Mingshui Economic Development District, Zhangqiu, Jinan City

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:

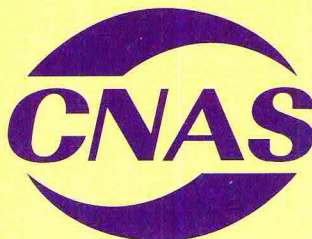
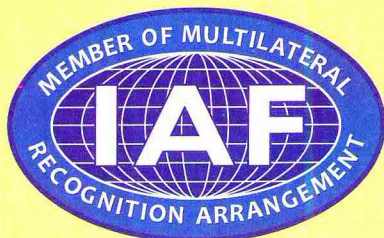
The Design, Development, Production and Service of biological safety cabinet;  
BYKG series air segregation equipment; QP series carbon dioxide incubator; BDF  
series freezer; laminar flow cabinet; centrifuge; fume hood; PCR cabinet; dispensing  
booth.

**Date of issue:** July 22, 2019

**Date of expiry:** July 21, 2022

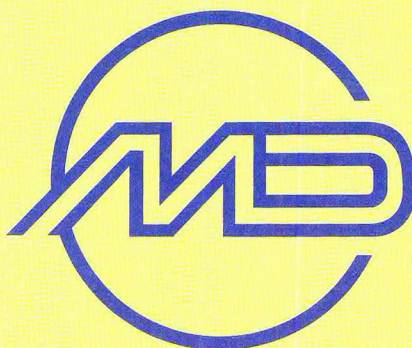
**General Manager:**

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



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

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



REGISTRATION NO. 04719Q10000898

## **CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES**

This is to certify that the quality management system of

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

**Registered Address:** Floor 5, Science and Technology Incubator Building, No. 6  
Lanxiangzhong Road, Tianqiao District, Jinan City

**Postcode:** 250000

**Manufacturing Address:** No. 51 South Gongye Road, Jinan City; North Side of  
Jiwang Road, Mingshui Economic Development District, Zhangqiu, Jinan City

**Has been assessed and conformed to the following standard(s)**

**YY/T 0287-2017 idt ISO 13485:2016**

**The certificate is valid for the following scope:**

**The Design, Development, Production and Service of biological safety cabinet;  
BYKG series air segregation equipment; QP series carbon dioxide incubator; BDF  
series freezer; laminar flow cabinet; centrifuge; fume hood; PCR cabinet; dispensing  
booth.**

**Date of issue:** July 22, 2019

**Date of expiry:** July 21, 2022

**General Manager:**

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

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)) or the website of CMD ([www.cmdc.com.cn](http://www.cmdc.com.cn)). Address: 5<sup>th</sup> floor of Zhong Lian building, No. Jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993