

CELAB®

Via Maira snc
04100 Latina
Italy
celab@celab.com



CERTIFICATE

Certificate Number **UCN** : **802497389091**
Job : J27439
Date of Issue : 2019-09-09
Certificate valid up to : 2023-09-08

Brand Name : See Label
Type : Automatic chemistry analyzer
Model N : BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280, BK-200, BK-200mini


Manufacturer : Biobase Biodustry(Shandong) Co., Ltd
Address : Biobase Industry Park, Crossing of Jingshi East Road and Mingbu Road,
Mingshui Economic Development Zone, Zhangqiu, Jinan City Shandong Province, China

Standard Used : EN 60601-1:2006+A1:2013

Conclusion :

*After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)*

*This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:*

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : ESC-BBBS-2019-09-1C	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

Copyright of this Certificate is owned by CELAB® Italy and may not be reproduced other than in full and with the prior approval of the General Manager. Use of this certificate is subjected to Celab regulation available on Celab web site.

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

www.celab.com

CERTIFICATE

Certificate Number **UCN** : **802497389091**

Job : J27439

Date of Issue : 2019-09-09

Certificate valid up to : 2023-09-08

Brand Name : See Label

Type : Automatic chemistry analyzer

Model N : BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280, BK-200, BK-200mini

Manufacturer : Biobase Biodustry(Shandong) Co., Ltd

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

Standard Used : EN 60601-1:2006+A1:2013


Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:

93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity	✓ OK
Test report reference : ESC-BBBS-2019-09-1C	
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

Copyright of this Certificate is owned by CELAB® Italy and may not be reproduced other than in full and with the prior approval of the General Manager. Use of this certificate is subjected to Celab regulation available on Celab web site.

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com



BIOBASE

Biobase Disinfection (Shandong) Co.,Ltd.

ADD: Room 303, R&D Building,OLABO Intelligent Manufacturing Industrial Park,

No. 1, Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong

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

Pressure Equipment Directive 2014/68/EU-Annex III have been taken as reference for these processes

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

Room 303, R&D Building,OLABO Intelligent Manufacturing Industrial Park,
No. 1, Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong

Related Directives and Annex: Pressure Equipment Directive 2014/68/EU

Product(s): **Autoclave**

Type(s)/Model(s): BKM-Series, BKQ-Series, BK-Y-Series, BK-B-Series, HAS-Series, BKS-Y

Classification: **Laboratory Equipment**

Examination Period: **May 23, 2022**

Date of Expiry: **May 22, 2027**

Review Result: We, Biobase Disinfection (Shandong) Co.,Ltd. declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Pressure Equipment Directive 2014/68/EU was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

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

RA Specialist:

Ajen Wang

Document No: **BKSD-W22052302**



BIOBASE

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

Medical Devices Regulation 2017/745 (EU) has been taken as reference for these processes

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

Examination Intent: Examination the completeness of the Technical Documentation according to the requirements of Annex II excluding section 4 (Module H) of 2017/745 (EU)

Harmonised Standards: EN 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016

Product(s): Autoclave

Type(s)/Model(s): BKM-Z24B(III), BKM-Z45B(III), BKQ-Z100H

Classification: I (according to the classification rules of the MDR)

Examination Period: July 8, 2021

Date of Expiry: July 7, 2026

Review Result: We, Biobase Disinfection (Shandong) Co., Ltd, declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of Annex II excluding section 4 (Module H) of 2017/745 (EU) has been detected.

Year of DOC marking: 2021

Signed for and on behalf of

Company: Biobase Disinfection (Shandong) Co., Ltd

RA Specialist: 

Document No: MDR-Z21070807



BIOBASE

JINAN BIOBASE MEDICAL CO.,LTD.
ADD:NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, 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 have been taken as reference for these processes

Company Name: JINAN BIOBASE MEDICAL CO.,LTD.
NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, JINAN,
SHANDONG,CHINA.

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): **Centrifuge**

Type(s)/Model(s): **BKC-TL4MII**

Classification: **Laboratory Equipment**

Examination Period: **June 16, 2022**

Date of Expiry: **June 15, 2027**

Review Result: We, JINAN BIOBASE MEDICAL 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.

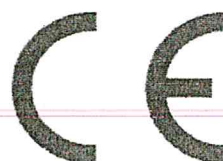
Year of DOC marking: **2022**

Signed for and on behalf of

Company: JINAN BIOBASE MEDICAL CO.,LTD.

RA Specialist: *Chloe Cheng*

Document No: SD-CC22061601



BIOBASE

BIOBASE BIODUSTRY (SHANDONG) CO., LTD.

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

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**
Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

SRN: CN-MF-000025015

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): Constant-Temperature Incubator

Type(s)/Model(s): BJPX-H50IV, BJPX-H80IV, BJPX-H160IV, BJPX-H270IV, BJPX-H30II, BJPX-H48II
BJPX-H64II, BJPX-H123II, BJPX-H230II

Classification: Laboratory Equipment

Examination Period: June 16, 2022

Date of Expiry: June 15, 2027

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.

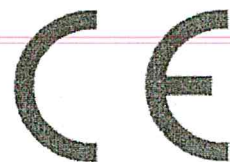
Year of DOC marking: **2022**

Signed for and on behalf of

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

RA Specialist: *Chloe Cheng*

Document No: **BKSD-CC22061603**



Version: BKSD2022 LVD & EMC DOC 1.0

BIOBASE

BIOBASE BIODUSTRY (SHANDONG) CO., LTD.

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

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**
Mingshui Economic Development Zone, Zhangqiu District,
Jinan City, Shandong, China (Biobase Industrial Park in a
intersection of East Jingshi Road and Mingbu Road)

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): **Multi-function Biological Microscope**

Type(s)/Model(s): **BMM-1000, BMM-2000**

Classification: **Laboratory Equipment**

Examination Period: **March 24, 2022**

Date of Expiry: **March 23, 2027**

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: **2022**

Signed for and on behalf of

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

RA Specialist: 

Document No: **BKSD-CC22032403**





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

In Vitro Diagnostic Medical Devices Directive 98/79/EC has 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

Relevant Directive: **In Vitro Diagnostic Medical Devices Directive-IVDD 98/79/EC**

Product(s): **Semi-auto Chemistry Analyzer**

Type(s)/Model(s): **BIOBAE-Silver**

Harmonised standard(s): **EN 61010-2-101:2002; EN 61326-2-6:2006; EN ISO 15223-1:2016;
EN ISO 13485:2016; EN ISO 14971:2012; EN ISO 18113-1:2011;
EN ISO 18113-3:2011; EN 62366:2008**

Classification: **others (according to In Vitro Diagnostic Medical Devices Directive)**

Examination Period: **March 31, 2021**

Date of Expiry: **March 30, 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 Annex II & III of IVDD 98/79/EC has been detected.**

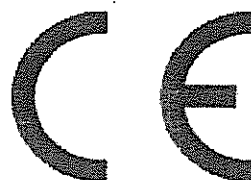
Year of DOC marking: **2021**

Signed for and on behalf of

Company: **BIOBASE BIODUSTRY (SHANDONG) CO., LTD.**

RA Specialist: Zaner Qu

Document No: **BKIVD-Z21033101**





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

Manufacturing Address: North Side of Jiawang 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)
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; 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.**

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certification No. : HXC18921YL008R0M

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 Medical Devices Quality Management Systems of the above
Organization has been assessed and Found to be in accordance with
the requirements of the standard:**

ISO 13485:2016

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
------------	-----------	-------------	-----------	------------	-----------

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.



张建国



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