



# 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/A1:2019, EN 61326-1:2013

Product Name : Centrifuge

Report No and Date : EC.BIOBASE.20220119006-R-1

Product Brand/Model/Type : See Annex Page

Certificate Number : M.2021.206.C71003

Initial Assessment Date : 24.01.2022

Registration Date : 25.01.2022

Reissue Date/No : -

Expiry Date : 24.01.2027

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

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# CERTIFICATE

## ANNEX of Certificate No: M.2021.206.C71003

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-IC, 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-IC, 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-18CI, TDL-5AT, TD-5BT, TDL-5KT, DD-5KT, DD-5BT, DDL-5KT, DD-5IT, TDL-6M, DD-5K, DD-5KC, DDL-6RC, DDL-5MC, DDL-5M, BKC-VL5RMB, TD-5A, BKC-TL5MA, Mini-6, Mini-8, Mini-10, TD-3, BKC-MC3, BKC-BB6A, BKC-BB7, BKC-TB12, BKC-TB4KIL, BKC-OIL5B, BKC-PRP5, BKC-TH16D, BKC-TH16RD, Mini-10K, Mini-10K+, D2012 plus, LC-HD, LC-4KII, LC-H4KII, LC-4KA, LC-4K-2, LC-5K, LC-4KB, LC-4KC, LC-T4K, LC-H4K, BKC-TL4B, BKC-TL4MII, BKC-TL4, BKC-TL4II, BKC-TL4III, BKC-TL5III, BKC-TL5IV, BKC-TL5, BKC-TL5II, BKC-TL6, BKC-TL6II, BKC-TL5L, BKC-TL5RIV, BKC-TL6R, BKC-TL8R, BKC-VL5R, BKC-VL6R, BKC-VL8R, BKC-VL6RL, BKC-VL8RL, BKC-TL4IV, BKC-TL5VII, BKC-TL5R, BKC-TL5RL, BKC-VL6RLII, BKC-TL5LII, BKC-TL5V, BKC-TL5VI, BKC-TL6III, BKC-TL6IV, BKC-TL5RII, BKC-TL5RIII, BKC-TL16RE, BKC-MH16, BKC-TH16, BKC-TH18, BKC-TH16RII, BKC-TH20RII, BKC-TH16R, BKC-TH20R, BKC-TH12R, BKC-TH24RII, BKC-VH20R, BKC-VH21RII, BKC-VH20RII, BKC-VH10RL, BKC-TH20RL, BKC-TH16II, BKC-TH16RII, BKC-TH20RII, BKC-TH21RL, BKC-TH18II, BKC-TH21, BKC-TH18R, BKC-VH21RI, BKC-TH23RII, BKC-TH24R, BKC-TH24RL, BKC-HC12B, BKC-PCR16, BKC-AU4, BKC-AU5, BKC-AU5R, BKC-GC12, BKC-GC24, BKC-MF5A, BKC-MF5B, BKC-MF5C, BKC-BB6

  
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Product Brand/Model/Type : See Annex Page

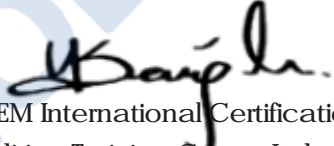
Certificate Number : M.2021.206.C71003

Initial Assessment Date : 24.01.2022

Registration Date : 25.01.2022

Reissue Date/No : -

Expiry Date : 24.01.2027

  
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# CERTIFICATE

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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



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  
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*

Biobase Disinfection (Shandong) Co., Ltd.

Sede Legale  
*Registered office*

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

Sede Operativa  
*Headquarters*

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

Apparecchio/insieme  
*Equipment/assembly*

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

Firma autorizzata  
*Authorized signature*

Timbro



*Amanda Payne*  
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**

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

# 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](http://www.cnca.gov.cn).

For the validity of the certificate, please scan the QR codes on the right side 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

# 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
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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](http://www.cnca.gov.cn).

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



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