



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





# 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**

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

The validity of the certificate can be checked through [www.udem.com.tr](http://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](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)





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

## 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 : North Side of Jiwang Road, Mingshui Economic Development  
District, Zhangqiu, Jinan City, Shandong, China

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 61010-1:2010, EN 61326-1:2013**

Product Name : **Freeze Dryer**

Report No and Date : **TMELMJ19030730031**

Product Brand/Model/Type : **BK-FD10S, BK-FD10P, BK-FD10T, BK-FD10PT, BK-FD12S, BK-FD12P,  
BK-FD12T, BK-FD12PT, BK-FD18S, BK-FD18P, BK-FD18T, BK-FD18PT,  
BK-FD20S, BK-FD20T, BK-FD30S, BK-FD30T, BK-FD50S, BK-FD50T,  
BK-FD100S, BK-FD100T**

Certificate Number : **M.2019.206.C0462**

Initial Assessment Date : **22.03.2019**

Registration Date : **25.03.2019**

Reissue Date/No : **-**

**Expiry Date : 24.03.2024**

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

The validity of the certificate can be checked through [www.udem.com.tr](http://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](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.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](http://www.entecerma.it). This Certificate of Compliance can be checked for validity at [www.entecerma.it](http://www.entecerma.it)

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

Additional information, clarification about the € 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



# 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

Scadenza- Expiry date 25/06/2021



Firma autorizzata

Authorized signature

*[Signature]*

Amanda Payne  
(Deputy Manager)

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**

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# 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

Firma autorizzata

*Authorized signature*

Timbro



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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**Ente Certificazione Macchine srl**

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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(Production); No.51, South Gongye Road, Jinan City, Shandong Province, China(Sale)

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 kit(see attachment for details), biosafety cabinet, medical aerosol absorber, pressure steam sterilizer, blood bank refrigerator, microbial incubator and automated ELISA processor(within the scope of license 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](http://www.cnca.gov.cn))  
SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



015

Certificate Number **45014**

Date: 09 July 2018  
Valid Until: 09 July 2021  
EAC Code: 19







## Biobase Biodustry (Shandong) Co., Ltd.

### Annex I

1. Triglyceride detection kit (enzyme colorimetric method)
2. Low density lipoprotein cholesterol test kit (direct method)
3. High-density lipoprotein cholesterol test kit (direct method)
4. Total cholesterol test kit (enzyme colorimetric method)
5. Creatine kinase isoenzyme detection kit (IFCC recommended method)
6. Total bilirubin test kit (dialysis-2,4-dichloroaniline colorimetric method)
7. Alanine aminotransferase detection kit (IFCC recommendation method)
8. Cholinesterase detection kit (butyryl thiocholine method)
9. Glucose detection kit (oxidase method)
10. Chlorine detection kit (mercury thiocyanate colorimetric method)
11. Magnesium detection kit (colorimetric method)
12. Carbon dioxide detection kit (enzymatic method)
13. Inorganic phosphorus detection kit (colorimetric method)
14. Apolipoprotein A1 detection kit (immunotransparency turbidity method)
15. Glucose detection kit (hexose kinase method)
16. Creatinine test kit (enzymatic method)
17. Calcium detection kit (arsenazo III method)
18. Glycosylated serum protein detection kit (two points method)
19. Lipoprotein (a) detection kit (immunotransparency turbidity method)
20. Total protein detection kit (biuret method)
21. Aspartate aminotransferase detection kit (IFCC recommended method)
22. Alkaline phosphatase test kit (IFCC recommended method)
23. Albumin detection kit (bromocresol green method)
24. Apolipoprotein B detection kit (immunotransparency turbidity method)
25. Urea detection kit (urease-glutamate dehydrogenase method)

Managing Director



Certificate Number **45014**

Date: 09 July 2018  
Valid Until: 09 July 2021  
EAC Code: 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.





## Biobase Biodustry (Shandong) Co., Ltd.

### Annex II

26.  $\alpha$ -amylase detection kit (EPS-G7 method)
27.  $\alpha$ -hydroxybutyrate dehydrogenase detection kit (DGKC recommended method)
28. Rheumatoid factor detection kit (immunotransparency turbidity method)
29. Total bile acid detection kit (circulating enzyme method)
30.  $\gamma$ -glutamyl transferase detection kit (SZASZ method)
31. Lactate dehydrogenase detection kit (DGKC recommended method)
32. Direct bilirubin test kit (diazotization-dichloroaniline colorimetric method)
33. Adenosine deaminase detection kit (enzymatic method)
34. Creatine kinase test kit (IFCC recommended method)
35. Creatinine test kit (bitter acid method)
36. Urine microalbumin detection kit (immunotransparency turbidity method)
37. Uric acid detection kit (TBHBA method)
38. Total cholesterol test kit (oxidase method)
39. Sodium detection kit (enzymatic method)
40. Potassium detection kit (enzymatic method)
41. Serum iron detection kit (pyrazine method)
42. Zinc test kit (colorimetric method)
43. Copper detection kit (colorimetric method)
44. 5'-ribonucleotide hydrolase detection kit (colorimetric method)
45. Monoamine oxidase detection kit (colorimetric method)
46. Alpha-fetoprotein detection kit (immunoturbidimetry)
47. Ammonia detection kit (glutamate dehydrogenase two-point method)
48. Leucine aminopeptidase detection kit (colorimetric method)
49. Cystatin C detection kit (immunoturbidimetry)
50.  $\beta$ 2-microglobulin detection kit (latex enhanced immunoturbidimetry)

*M. Combs*

Managing Director



Certificate Number **45014**

Date: 09 July 2018  
Valid Until: 09 July 2021  
EAC Code: 19







## Biobase Biodustry (Shandong) Co., Ltd.

### Annex III

51. N-acetyl- $\beta$ -D-glucosaminidase detection kit (colorimetric method)
52. Triglyceride detection kit (oxidase method)
53. Homocysteine detection kit (enzymatic method)
54. Apolipoprotein E test kit (immunoturbidimetry)
55. Phospholipid test kit (oxidase method)
56. Glucose detection kit (glucose oxidase method)
57. Glycosylated hemoglobin detection kit (enzymatic method)
58. D3 hydroxybutyric acid detection kit (enzymatic method)
59. Lactic acid test kit (enzyme color method)
60. Myoglobin detection kit (immunoturbidimetry)
61. Angiotensin converting enzyme detection kit (colorimetric method)
62. Lactate dehydrogenase isoenzyme 1 detection kit (lactic acid matrix rate method)
63. Lipase detection kit (enzyme coloring method)
64. Pepsinogen I detection kit (immunoturbidimetry)
65. Pepsinogen II detection kit (immunoturbidimetry)
66. Anti-streptococcus O detection kit (immunoturbidimetry)
67. High-sensitivity C-reactive protein detection kit (immunoturbidimetry)
68. Pre-albumin detection kit (immunoturbidimetry)
69. Transferrin detection kit (immunoturbidimetry)
70. Glucose-6-phosphate dehydrogenase detection kit (UV rate method)
71. D-dimer detection kit (immunoturbidimetry)
72. Complement C3 detection kit (immunoturbidimetry)
73. Complement C4 detection kit (immunoturbidimetry)
74. Immunoglobulin IgA detection kit (immunoturbidimetry)
75. Immunoglobulin IgG detection kit (immunoturbidimetry)

Managing Director



Certificate Number **45014**

Date: 09 July 2018  
Valid Until: 09 July 2021  
EAC Code: 19







## Biobase Biodustry (Shandong) Co., Ltd.

### Annex IV

76. Immunoglobulin IgM detection kit (immunoturbidimetry)
77.  $\alpha$ 1-acid glycoprotein detection kit (immunoturbidimetry)
78.  $\alpha$ 1-antitrypsin detection kit (immunoturbidimetry)
79. Ethanol detection kit (enzymatic method)
80. Apolipoprotein A2 detection kit (immunoturbidimetry)
81. Apolipoprotein C2 detection kit (immunoturbidimetry)
82. Apolipoprotein C3 detection kit (immunoturbidimetry)
83. Anti-thrombin III detection kit (immunoturbidimetry)
84. B factor detection kit (immunoturbidimetry)
85. C-reactive protein detection kit (immunoturbidimetry)
86. Direct bilirubin detection kit (vanadate oxidation method)
87. Direct bilirubin detection kit (oxidase method)
88. Fibrinogen detection kit (immunoturbidimetry)
89. Ferritin detection kit (latex enhanced immunoturbidimetry)
90. Fiber binding protein detection kit (immunoturbidimetry)
91. Glutamate dehydrogenase detection kit (enzymatic method)
92. Glycyl valine dipeptidyl aminopeptidase detection kit (enzymatic method)
93. Glycosylated hemoglobin detection kit (latex enhanced immunoturbidimetry)
94. Homocysteine detection kit (enzymatic method)
95. Immunoglobulin E detection kit (immunoturbidimetry)
96. Ischemic modified albumin detection kit (colorimetric method)
97. Aspartate aminotransferase mitochondrial isoenzyme detection kit (enzyme inhibition method)
98. Plasminogen detection kit (immunoturbidimetry)
99. Retinol binding protein detection kit (immunoturbidimetry)
100. Total bilirubin test kit (vanadate oxidation method)

*M. Combs*

Managing Director



Certificate Number **45014**

Date: 09 July 2018  
Valid Until: 09 July 2021  
EAC Code: 19





**Biobase Biodustry (Shandong) Co., Ltd.****Annex V**

101. Total bilirubin test kit (oxidase method)
102. Troponin I test kit (latex enhanced immunoturbidimetry)
103. Unsaturated iron binding force detection kit (Ferene method)
104. Urine total protein detection kit (colorimetric method)
105.  $\alpha$ 1-microglobulin test kit (latex enhanced immunoturbidimetry)
106. Fibrin and fibrinogen decomposition product determination kit (latex immunoturbidimetry)
107. Haptoglobin assay kit (immunoturbidimetry)
108. Procalcitonin assay kit (latex immunoturbidimetry)
109. Glycocholic acid assay kit (latex immunoturbidimetry)
110. Free fatty acid determination kit (ACS-PAP method)
111. Glycated albumin assay kit (peroxidase method)
112.  $\alpha$ 2 macroglobulin determination kit (immunoturbidimetry)
113. Heart-shaped fatty acid binding protein assay kit (latex immunoturbidimetry)
114. Anti-cyclic citrullinated peptide antibody assay kit (latex immunoturbidimetry)
115. Neutrophil gelatinase-related lipocalin assay kit (latex immunoturbidimetry)
116. Sialic acid assay kit (neuraminidase method)

Managing Director

Certificate Number **45014**

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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 : **Fume Hood**

Report No and Date : **OUCE-SH-163282-02-LVD/EMC**

Product Brand/Model/Type : **FH1000, FH1200, FH1500, FH1800, FH1000(X), FH1200(X), FH1500(X),  
FH1800(X), FH1000(A), FH1200(A), FH1500(A), FH1800(A), FH1000(W),  
FH1200(W), FH1500(W), FH1800(W), FH1000(P), FH1200(P), FH1500(P),  
FH1800(P), FH1000(E), FH1200(E), FH1500(E), FH1800(E)**

Certificate Number : **M.2016.201.Y2308**

Initial Assessment Date : **07.12.2016**

Registration Date : **08.12.2016**

Reissue Date/No : **-**

  
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