



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)

*M Combsley*

Managing Director

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 (diazo-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)

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## 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 (diazo-2,4-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)

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## 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)

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**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)

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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)

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 Managing Director

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