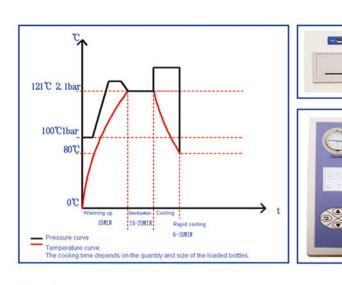


Vertical Autoclave

This vertical autoclave is especially designed for liquid and food sterilization in laboratory, pharmaceutical and food facotry.





Features:

- * Standard build-in printer.
 * Deionized water interface for supplying steam generator.
- * With a guick maintenance window, the electrical parts can be repaired without removing the cover.
- * Microcomputer control. Fully automatic control water injection, temperature rise, sterilization, exhaust and dry.
- * LCD screen display shows pressure, temperature, time, running status, error codes and operation curve etc.
- * Mobile probe detects the internal temperature of liquid directly, to ensure the sterilization effect of liquid program.

Technical Parameters:

Model	BKQ-B50L	BKQ-B75L	
Capacity	50L	75L	
Chamber Size(mm)	φ386*490	φ386*670	
Chamber Material	SUS304		
Designed Pressure	0.28Мра		
Designed Temp	150℃		
Working Pressure	0.22MPa		
Working Temp.	80℃~136℃		
Temp. Display Accuracy	0.1℃		
Noise	≤65dB		
Consumption	5.5KW		
Power Supply	AC110/220V±10%, 50/60Hz		
SS Basket	1 pc		
External Size(W*D*H)mm	700*610*1100		
Package Size(W*D*H)mm	800*715*1270		
Gross Weight(kg)	140	147	

Vertical Pulse Vacuum Autoclave





Features:

- * Pulse vacuum exhaust to ensure the effect of steam sterilization.
- * Mobile probe detects the internal temperature of liquid directly, to ensure the sterilization effect of liquid program.
- * Efficient vacuum pumping system. The ultimate vacuum can reach more than -90KPa. Low noise, fast pumping speed, good dryness. The sterilization is more thorough.
- * LCD screen display shows pressure, temperature, time, running status, error codes and operation curve etc.
- * Selectable programs for packed, unpacked, dressings, rubber, liquid, liquid custom, solid custom, sterilization of medium, dissolution of medium, B&D testing and vacuum testing etc.
- * Complete process of preheating, replacement, pulse exhaust, heating, sterilizing and drying run automatically.
- * 0.22µm Sterilization high efficiency air filter. The filtration efficiency is higher than 99.5%, ensuring that the vacuum-depleted air is sterile air to prevent re-pollution of sterile materials.
- * Standard built-in printer for recording the information during the entire sterilization process.

Technical Parameters:

Model	BKQ-B50V	BKQ-B75V	
Capacity	50L	75L	
Chamber Size(mm)	φ386×490	φ386x670	
Design Pressure	-0.1~0.28MPa		
Chamber Material	SUS304		
Design Temperature	142℃		
Vacuum System	Eject vacuum system		
Working Temp.	105~137°C		
Consumption	5.5KW		
Power Supply	AC110/220V±10%, 50/60Hz		
Environment Temperature	5~40°C		
SS Basket	1 pc		
External Size(W*D*H)mm	700*610*1100		
Package Size(W*D*H)mm	800*715*1270		
Gross Weight(kg)	150 155		

Note: It is applicable to the altitude below 3,500m

BIOBASE®

Washer Disinfector (Lab Automatic Glassware Washer)





BK-LW120

BK-LW220/320

BK-LW420

Introduction:

The lab glassware washers integrate programmed cleaning, disinfecting and drying functions to clean all glassware stuff, for beaker, flask, pipette, petri dish, burette, measuring cylinder, test tube etc.

Features:

- * High efficient cleaning system, designed with European reliable pump, optimized spray arm and nozzles, and self-cleaning program;
- * Rapid and efficient drying system, designed with independent air heater, HEPA filter and drying process;
- * Water heating temperature can reach 99°C, while hot air drying temperature can reach 120°C;
- * Professional configuration design—stainless steel for corrosion resistance; reinforced glass window mounted to achieve a clear view on washing process;
- * PLC touch screen control with preset 12 programs and 99 cutomized programs
- * Safety protection—electronic security door lock to prevent unexpected door opening, water & drying air temperature dual control and equipped with emergency switch.

Standard Washing Procedure (can be self-designed by the user):

Pre-cleaning→Washing with cleaner→Rinse→Washing with neutralization→Rinse→Washing with hot water→Drying

All cleaning racks can be removed completely, convenient to washing rack pipeline:



Standard Rack (BKIR36)



Beaker Rack (BKBR01)



Combined Rack (BKIR11218)



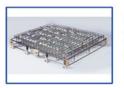
Measuring
Cylinder Rack
(BKIR38)



Injection Rack (BKIR30)



Petri-dish Rack-Lower (BKPDR9075L)



Petri-dish Rack-Upper (BKPDR9075U)



Pipette Rack (BKPR60)



Rubber Tube Rack (BKRTR20)

Technical Parameters:

Model	BK-LW120	BK-LW220	BK-LW320	
Capacity	120L	220L	320L	
Water Consumption/Cycle	15L			
Inlet Water Pressure	0.03~0.8Mpa			
Noise	≤50dB	≤55dB		
Material	Internal materia: SS316, Outer material: SS304			
Overall Power Consumption	6KW	6.5/16.5KW	6.5/18KW	
Power Consumption-Water Washing	0.75KW 1.5		1.5 KW	
Power Consumption-Water Heating	5KW 5/15KW			
Power Consumption-Drying	2.1KW	3.6KW		
Power Supply	AC220V, 50Hz AC220V, 50Hz; 380V, 50Hz			
Cleaning Racks	1 pcs	2 pcs	3 pcs	
Standard Cleaning Racks	BKIR36*1	BKIR36*2 BKIR36*3		
Standard Accessories	One bucket RBS A 155 leaner (1 L), One bucket RBS A 375 neutralizer (1 L)			
Optional Accessories	USB interface, printer, Cleaning racks			
Washer Chamber Size(W*D*H)mm	600*629*465	600*629*658	600*629*820	
External Size(W*D*H)mm	960*740*850	780*690*1760	790*690*1950	
Package Size(W*D*H)mm	1100*950*1050	1000*850*2100	1000*840*2180	
Gross Weight(kg)	145	330	350	



Table Top Autoclave Class B Series

BKM-BIII series sterilizer is a Class B table top sterilizer. As a type of high pressure sterilizer, it takes steam as its sterilization medium which is fast, safe and economic. They are common used in stomatology department, ophthalmology department, operating room and CSSD to make the sterilization for wrapped or unwrapped instrument, fabric, utensils, culture medium, unsealed liquid, etc.



BKM-Z18B(III)/24B(III)/45B(III)



BKM-Z60B(III)/80B(III)

Features:

Built-in open type water tank

- a. Easy-clean open type water tank
- b. Water quality monitor
- c. Water filter inside
- d. Water level sensor
- e. A fully injected water tank can support repeated program running.



Brand-new operation interface

The LCD screen can display temperature, pressure, time, operating status, error and alarm information, etc. It is convenient for users to observe the sterilizer running status.

Multiple security protective device

Over temperature automatic protective device, multiple control and protection for steam generator, door safety interlock protection and dual chamber overpressure protection, electronic circuit safety device.

Automatic door

BKM-Z18/24/45BIII series adopt automatic door structure, fast and simple operation, protecting operators from scald. BKM-60/80BIII series adopt multipoint synchronous linkage pressing technology, reliable and durable.

Efficient vacuum

Efficient vacuum system, low working noise, vacuum lowest limit can reach over -90KPa, vacuum in high speed, perfect drying performance, thorough sterilization.

Multiple program types

Sterilization programs: Unwrapped, wrapped, rubber, user 01, N-quick, B-quick, prion test program: BD& Helix,

Leakage test.

Auxiliary program: Preheat, drying, washing.

High-efficiency steam generator

BKM-Z18/24/45BIII adopt build-in instant steam generator. BKM-60/80BIII adopt build-in energy-storing type steam generator producing steam in high speed and large quantity.

Other features

Pulse vacuum, heating, sterilization, exhausting, vacuum drying totally automatic.

The chamber is heated by film heater, saving energy and time.

Record type: built-in printer (Standard)

Electronic storage: USB flash disk (Optional)

Loading tray



Type A



Type B



Type C (Optional for 45/60/80L)

Technical Parameters:

Model	BKM-Z18B(III)	BKM-Z24B(III)	BKM-Z45B(III)	BKM-Z60B(III)	BKM-Z80B(III)
Capacity	18 L	24L	45L	60L	80L
Chamber Size(mm)	φ250*350	φ250*450	φ316*618	φ386*595	φ386*717
Design Pressure	-0.1/0.3MPa				
Design Temp.	144℃				
Temp. Range	105~138℃				
Chamber Material	SUS304				
Standard Loading Tray	Туре А		Туре В		
Consumption	2.6KW		5.8KW	7.4KW	
Power Supply	AC110/220V±10%, 50/60Hz		AC220V±10%, 50/60Hz		
External Size(W*D*H) mm	530*560*450	530*660*450	640*830*550	730*1002*560	730*1002*560
Package Size(W*D*H) mm	720*780*680	720*880*700	750*1015*730	830*1180*795	830*1180*795
Gross Weight(kg)	70	80	140	185	205



EC DECLARATION OF CONFORMITY

We, **Biobase Biodustry (Shandong) Co., Ltd,**No. 51 South Gongye Road, Jinan City, Shandong Province, P.R. China

herewith declare that the blow mentioned product meets the provisions of the **Council Directive**93/42/EEC for Medical Device Directive (MDD). All supporting documention is retained under these premises and/or the premises of manufacture's subcontractors.

Product Name: Pressure Steam Autoclave

Model: BKM-Z18N, BKM-Z24N, BKM-Z16B, BKM-Z18B, BKM-Z24B, BKM-Z18B(III), BKM-Z24B(III), BKM-Z45B(III), BKM-Z60B(III), BKM-Z80B(III), BKM-Z24S, BKM-Z45S, BKM-Z80S, BKQ-Z30I, BKQ-Z50I, BKQ-Z75I, BKQ-Z100I, BKQ-B50(II), BKQ-B75(II), BKQ-B100(II), BKQ-B120(II), BKQ-B150(II), BKQ-B200(II), BKQ-B50V, BKQ-B75V, BKQ-H150, BKQ-H200, BKQ-H300, BKQ-H400, BKQ-H500, BKQ-B100(H), BKQ-B150(H), BKQ-Z300(H)

Classification: **IIb** (according to classification rules in Annex IX of 93/42/EEC)

GMDN: Sterilizer, moist heat, fluid / 41450

Conformity Assessment Rout: Annex II excluding section 4(Module H)

Relevant harmonised standards: see the attachment

This DECLARATION OF CONFORMITY is valid in connection with the release document for the respective serial of produced devices.

The DECLARATION OF CONFORMITY is only valid in connection with a batch specific Certificate of compliance for the above products concerned bearing the CE mark.

Date of CE marking: April 18, 2019

Signed for and on behalf of

Company:

Biobase Biodustry (Shandong) Co., Ltd.

General Manager:

Document No:

BKMDD-190418





Attachment

For the Relevant Harmonised Standards

Standard	Title		
EN 13060:2014	Small steam sterilizers		
EN 14180:2003+A2:2009	Sterilizers for medical purposes - Low temperature steam and		
	formaldehyde sterilizers - Requirements and testing		
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements		
EN ISO 13485:2016/AC:2016	for regulatory purposes (ISO 13485:2016)		
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device		
	labels, labelling and information to be supplied - Part 1: General		
	requirements (ISO 15223-1:2016, Corrected version 2017-03)		
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and		
	testing within a risk management process		
EN ISO 14971:2012	Medical devices - Application of risk management to medical		
	devices		
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device		
	labels, labelling and information to be supplied - Part 1: General		
	requirements		
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements		
	for safety - Collateral standard: Safety requirements for medical		
	electrical systems		



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)

SNQA's website: www.snqa.com.cn

Monday

Certificate Number

45014

Managing Director

U K A S MANAGEMENT Date:

09 July 2018

Valid Until:

09 July 2021

EAC Code:





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)

Monday

Managing Director

Certificate Number

45014



Date:

09 July 2018

Valid Until:

09 July 2021

EAC Code:





Annex II

- 26. α-amylase detection kit (EPS-G7 method)
- 27. α-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. y-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. β2-microglobulin detection kit (latex enhanced immunoturbidimetry)

n Comoter

Managing Director

Certificate Number

45014



Date:

09 July 2018

Valid Until:

09 July 2021

EAC Code:





Annex III

- 51. N-acetyl-β-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)

Monday

Managing Director



45014

Managing Director

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

C Code: 19







Annex IV

- 76. Immunoglobulin IgM detection kit (immunoturbidimetry)
- 77. al-acid glycoprotein detection kit (immunoturbidimetry)
- 78. α1-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)

Monday

Certificate Number

45014

Managing Director



Date:

09 July 2018

Valid Until:

09 July 2021

EAC Code:





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. α1-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. α2 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)

Manday

Managing Director



Certificate Number

45014

Date:

09 July 2018

Valid Until:

09 July 2021

EAC Code:

