

Laboratory Refrigerator



656L



1500L

Technical Parameters

Model	BPR-5V650	BPR-5V1500
External Size(W*D*H) mm	1220*642*1885	1880*775*1956
Capacity	656L	1500L
Temp. Range	2~8°C	
Temp. Accuracy	0.1°C	
Control System	Microprocessor Control & Large Screen LED Display	
Alarm	Audible and visual alarm for: High and lowtemperature, Thermostat fault , Door Ajar,Power Failure (only for BPR-5V650),senor fault (only for BPR-5V1500)	
Refrigeration Type	Forced air refrigeration system	
Refrigerant	R600a, CFC Free	R134a, CFC Free
Condenser&Evaporator	High efficiency air-cooled condenser, made of copper	
Defrost	Auto defrost	
Construction	Structure	Unibody design & Mono-assembly foaming (rigid polyurethane insulation material)
	Internal Material	Cold-rolled steel coated with anti-bacteria powder SS304
	External Material	Cold-rolled steel coated with anti-bacteria powder SS304
Shelves	Adjustable shelves made of high quality steel wire	
	10 pcs	12 pcs
Consumption	385W	1040W
Power Supply	AC110/220V±10%, 50/60Hz	
Standard Accessory	LED lamp, Shelves, Door keys, Testing hole, Battery	
Package Size(W*D*H) mm	1330*715*2000	1940*880*2035
Gross Weight	184kg	280kg

-25°C Freezer



BDF-25H305

Features

1. Digital temperature display.
2. The safety lock can prevent random opening.
3. Baskets made of steel wire are convenient to store articles.
4. Round corner design of doors and the body provides luxury and elegance.
5. Delayed start and safe stop interval between restart and being terminated, ensure reliable running.

Technical Parameters

Model	BDF-25H305	
External Size(W*D*H) mm	1148*740*872	
Capacity	305L	
Temp. Range	-10°C~-25°C	
Temp. Accuracy	0.1°C	
Control System	Microprocessor control&LED display	
Alarm	High or low temperature alarm, sensor failure alarm, thermostat alarm, power failure alarm	
Refrigeration Type	Direct refrigeration	
Refrigerant	R600a, CFC free	
Condenser&Evaporator	Internal-mounted condenser and coil type evaporator	
Construction	Structure	Whole foaming, freon cyclopentane/isopentane high density polyurethane foam
	Internal Material	Cold-rolled steel coated with anti-bacteria powder
	External Material	Cold-rolled steel coated with anti-bacteria powder
Basket	none	
Consumption	106W	
Power Supply	AC220V±10%,50/60Hz; AC110V±10%,60Hz	
Package Size(W*D*H)mm	1223*777*1005	
Gross Weight	87kg	

BA-B Series Electronic Analytical Balance (External Calibration)

Features:

- * Humanized design, novel design and five-side full-transparent windshield.
- * A new-generation electromagnetic balance weighing sensor guarantees high precision.
- * Application programs such as automatic fault detection, four-point linear calibration and over-load protection.
- * Ultra-large LCD display brings clearer and more comfortable visual sense to operate.



Functions:

- * Multiple functions guarantee easy and reliable operation, including auto-counting, unit conversion (metric carat, gold ounce, etc.), stability, full-scale faring, zero-memory, etc.
- * Built-in RS232C output interface guarantees direct connection to external equipment such as computer and printer.
- * Built-in lower weighing hook guarantees convenient use.

Power Supply: AC110/220V±10%, 50/60Hz; Power Cord, no battery.

Technical Parameters:

Model	Capacity	Readability	Scale Size	N.W.	External Size	Package Size	Work Space Height	Calibration
BA504B	0~50g	0.1mg	Φ80mm	6.8kg	350*215*340mm	480*375*515mm	240mm	External Cal
BA604B	0~60g							
BA1004B	0~100g							
BA1104B	0~110g							
BA1204B	0~120g							
BA1604B	0~160g							
BA2004B	0~200g							
BA2204B	0~220g							
BA2104B	0~210g							
BA2104S	0~60g 60~210g							

Standard Accessory:

Balance body, adapter, weight, windshield, cleaning cloth, tweezers and brush.

BP-B/P Series Electronic Precision Balance

Features:

- * Humanized design, novel design and five-side full-transparent windshield.
- * A new-generation electromagnetic balance weighing sensor guarantee high precision.
- * Application programs such as automatic fault detection, four-point linear calibration and over-load protection.
- * Ultra-large LCD display brings clearer and more comfortable visual sense to operate.
- * Built-in lower weighing hook guarantees convenient use.



Functions:

- * Multiple functions guarantee easy and reliable operation, including auto-counting, unit conversion (metric carat, gold ounce, etc.), stability, full-scale faring, zero-memory, etc.
- * Built-in RS232C output interface guarantees direct connection to external equipment such as computer and printer.
- * Built-in lower weighing hook guarantees convenient use.

Power Supply: AC110/220V±10%, 50/60Hz; Power Cord, no battery.

Technical Parameters:

Model	Capacity	Readability	Scale Size	N.W.	External Size	Package Size	Work Space Height	Calibration		
BP1003B	0~100g	1mg	Φ80mm	6.8kg	350*215*340mm	480*375*515mm	240mm	External Cal		
BP1203B	0~120g									
BP2003B	0~200g									
BP3003B	0~300g									
BP4103B	0~410g									
BP5003B	0~500g		Φ110mm	6kg						
BP10003	0~1000g									
BP1003P	0~100g								Φ80mm	6.8kg
BP2003P	0~200g									

Standard Accessory:

Balance body, adapter, weight, windshield, cleaning cloth, tweezers and brush.

Semi-auto Coagulation Analyzer COA01/COA02/COA04



COA01



COA04



COA02

Features:

- ①. Parameters: PT, APTT, TT, FIB, etc.
- ②. Principle: Clotting, optical method.
- ③. Precise electronic pipette.
- ④. Languages: English, French, Spanish, Portuguese, etc.
- ⑤. Automatic start reagent addition.
- ⑥. Thermal printer, auto & manual print.
- ⑦. LIS system available.

Reagent Parameters:

Item	Sample volume	Reagent 1	Reagent 2	Incubating time	CV%
PT	20μl	40μl	/	120s	≤5%
APTT	20μl	20μl	20μl	180s	≤5%
TT	30μl	30μl	/	120s	≤8%
FIB	40μl	20μl	/	180s	≤5%

Parameters:

Model	COA01	COA02	COA04
Testing Channel	1	2	4
Display	4.3"	5"	
Cuvette Incubation Positions	5	12	24
Reagent Incubation Positions	2	5	6
Wavelength	LED 470nm		
Sample Type	Plasma		
Results	10,000 results storage		
Sample Volume	20~40μl		
Available Units	Seconds, Ratio, %, g/L		
Incubation Temperature	37.0±1.0°C		
Relative Humidity	≤85%		
Precision	PT, APTT, FIB≤5%; TT≤8%(Normal sample)		
Deviation between Channels	≤5%		
Power Supply	AC100~240V, 50/60Hz		
External Size	290*260*135mm	345*325*145mm	375*335*175mm
Net Weight	2.1kg	4.5kg	5.2kg
Package Size	360*360*260mm	440*420*350mm	440*420*340mm
Gross Weight	6.5kg	7kg	7.5kg

-25°C Freezer



Technical Parameter:

Model	BDF-25V936
External Size(W*D*H) mm	1304*1000*2017
Internal Size(W*D*H) mm	1000*700*1335
Capacity	936L
Type	Vertical
Temp. Range	-10°C~-25°C
Temp. Accuracy	0.1°C
Control System	Microprocessor control ,LED display
LED Display Panel	LED digital display, can display the cabinet temperature, ambient temperature, condenser temperature, heat exchanger temperature, power supply voltage, battery power ,etc; LED working status indicator light, which can indicate: compressor running, setting temperature, calibration, setting high temperature alarm, low temperature alarm and other working status LED fault indicator, which can indicate: high temperature fault in the cabinet, low temperature fault in the cabinet, power off, door opening, sensor fault, low battery, condenser fouling, abnormal voltage, high temperature fault information.
Alarm	High and low temperature alarm, sensor fault alarm, temperature controller fault alarm, power off alarm, door opening alarm, ring temperature alarm, condenser fault alarm, filter screen inspection alarm, abnormal voltage alarm, battery low power alarm.
Refrigeration Type	High and low temperature alarm, sensor fault alarm, temperature controller fault alarm, power off alarm, door opening alarm, ring temperature alarm, condenser fault alarm, filter screen inspection alarm, abnormal voltage alarm, battery low power alarm.
Refrigerant	R404A, 320g
Compressor	Imported brand compressor, two sets
External material	Sprayed steel plate
Internal material	SS304
Insulation material	CFC-Free high density polyurethane foam, 150mm insulation material thickness
Outer & inner door insulation	CFC-Free high density polyurethane foam.
Chamber with Inner Door	4
Shelves /Drawers	3 layers, SS304 , with adjustable height and scale of clapboard.
Consumption	1000W
Standard accessories	USB port ,independent power switch, remote alarm function interface, 72 hours battery backup for power failure alarm , Φ18mm probe access hole
Optional accessories	Liquid nitrogen backup system, frozen rack, temperature recorder
Power Supply	198V ~ 242V range of normal use, 220V±10% , 50/60Hz
Package Size(W*D*H) mm	1360*1135*2170mm
Gross Weight	421kg

Table Top Low Speed Centrifuge



BKC-TL4



BKC-TL4II/TL4III

Features:

- * LCD display, microprocessor control.
- * Brushless motor: variable frequency.
- * Multiple layers shock absorbers, automatic balancing to achieve smooth running.
- * Can store 20 operation procedures.



8*20ml



24*10ml

Technical Parameters:

Model	BKC-TL4	BKC-TL4II	BKC-TL4III
Capacity	8*20ml	12*20ml, 18*10ml, 24*10ml	4*50ml, 12*15ml
Max. Speed	4000rpm		
Max. RCF	2200xg	2600xg	2100xg
Speed Precision	±30rpm		
Timing Range	0~99h59min inching function		
Noise	≤60dB		
Power Supply	AC110/220V, 50/60Hz		
External Size(W*D*H) mm	380*260*310	500*450*280	
Package Size(W*D*H) mm	550*410*510	700*630*480	
Net Weight(kg)	18	20	
Gross Weight(kg)	33	35	

Table Top Low Speed Centrifuge

Features:

- * LCD display, intelligent control, touchable and press button
- * Brushless motor: variable frequency
- * Stainless steel chamber
- * Mute mechatronics motor door lock
- * Special button for RCF control
- * Memory of last setting procedure
- * Can store 20 operation procedures
- * 10 levels speed-up and speed-down control



Technical Parameters:

Model	BKC-TL5III	BKC-TL5IV
Max. Capacity	4*250ml	4*250ml
Max. Speed	5500rpm	5000rpm
Max. RCF	4800×g	4800×g
Control and Driver System	Frequency motor, micro control, direct drive	
Timing Range	0~99h59min	
Noise	≤65dB	
Consumption	500W	
Power Supply	AC110V/220V, 50/60Hz	
External Size(W*D*H) mm	600*540*360	
Package Size(W*D*H) mm	700*581*475	
Net/Gross Weight(kg)	37/52	



12*10ml



4*250ml



8*50ml



48*5ml



32*15ml



Micro-plate rotor

Rotor:

Capacity	Capacity	BKC-TL5III		BKC-TL5IV	
		Speed(rpm)	RCF(xg)	Speed(rpm)	RCF(xg)
Angle Rotor	12*10ml	5500	4328	/	/
Swing Rotor	4*250ml	4000	3290	4000	3290
Adapter	8*50ml	4000	3290	4000	3290
	24*15ml				
	32*10ml				
	40*5ml				
Swing Bucket Rotor	8*50ml	4000	2810	4000	2810
	4*50ml	5000	4600	5000	4600
	4*100ml	5000	4800	5000	4800
	24*15ml	4000	2810	4000	2810
	32*15ml	4000	2810	4000	2810
	32*10ml	4000	2810	4000	2810
	48*5ml/2ml (Vacuum tube)	4000	2940	4000	2940
76*5ml/2ml (Vacuum tube)	4000	3100	4000	3100	
Microplate	2*2*96well	4000	2360	4000	2360

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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.**
No. 51 South Gongye Road, Jinan, Shandong Province, China

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

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

Type(s)/Model(s): **COA01, COA02, COA04**

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: December 21, 2018

Date of Expiry: December 20, 2023

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.

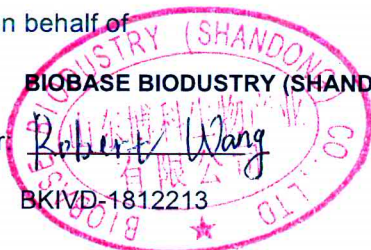
Year of DOC marking: **2018**

Signed for and on behalf of

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

General Manager: 

Document No: **BKIVD-1812213**



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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.**
No. 51 South Gongye Road, Jinan, Shandong Province, China

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

Product(s): **Table Top Low Speed Centrifuge**

Type(s)/Model(s): **BKC-TL4, BKC-TL4II, BKC-TL4IV, BKC-TL4V, BKC-TL5, BKC-TL5II, BKC-TL5V, BKC-TL5VI, BKC-TL5VII, BKC-TL6, BKC-TL6II, BKC-TL6III, BKC-TL6IV**

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 13532:2002; EN 13612:2002**

Classification: **others (according to classification rules in 98/79/EC)**

GMDN Code: **36465(Centrifuge, general-purpose laboratory)**

Examination Period: **April 28, 2019**

Date of Expiry: **April 27, 2024**

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: **2019**

Signed for and on behalf of

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

General Manager: *Robert Wang*

Document No: **BKIVD-1904289**



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DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Medical Devices Directive 93/42/EEC has been taken as reference for these processes

Company Name: **Biobase Bioindustry (Shandong) Co., Ltd.**
No. 51 South Gongye Road, Jinan, Shandong Province, China

Examination Intent: Examination the completeness of the Technical Documentation according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC

Harmonised Standards: **EN 60601-1-1:2001; EN 60601-1-2:2015; EN ISO 13485: 2016; EN ISO 15223-1: 2016**

Product(s): **Laboratory Refrigerator**

Type(s)/Model(s): 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

Classification: **I (according to the classification rules of the MDD)**

Examination Period: April 28, 2019

Date of Expiry: April 27, 2024

Review Result: We, Biobase Bioindustry (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 93/42/EEC has been detected.

Year of DOC marking: 2019

Signed for and on behalf of
Company: **Biobase Bioindustry (Shandong) Co., Ltd.**

General Manager: *Robert Wang*

Document No: **MDD-1904281**



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. This Certificate of Compliance can be checked for validity at www.entecerma.it

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

Additional information, clarification about the **CE** 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 Morino

Deputy Manager
Amanda Payne

Ente Certificazione Macchine Srl

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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



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 : No.51 South Gongye Road, Jinan, Shandong, China 250101

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 60204-1:2006+A1:2009+AC:2010**
EN 61010-1:2010, EN 61326-1:2013

Product Name : **Low Temperature Freezer**

Report No and Date : TELMJ201810082771

Product Brand/Model/Type : BDF-25H150, BDF-25H200, BDF-25H300, BDF-25H389,
BDF-25H525, BDF-25V259, BDF-25V450, BDF-25V268,
BDF-25V270, BDF-25V328, BDF-40V253, BDF-40V288,
BDF-40V288A, BDF-40V525, BDF-40V450, BDF-40V90,
BDF-40V270, BDF-40V268, BDF-40V328, BDF-40H100,
BDF-40H200, BDF-40H300, BDF-40H390, BDF-40H485,
BDF-60H58, BDF-60H118A, BDF-60H218, BDF-60H318,
BDF-60H458, BDF-86V158, BDF-86V340, BDF-86V936,
BDF-86V100, BDF-86V108, BDF-86V308, BDF-86V528,
BDF-86V540, BDF-86V388, BDF-86V398

Certificate Number : **M.2018.201.N7086**

Initial Assessment Date : 17.10.2018

Registration Date : 18.10.2018

Reissue Date/No : -

Expiry Date : 17.10.2023


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

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)

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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 Measuring Instruments Directives 2014/32/EU have been taken as reference for these processes

Company Name: **Biobase Bioindustry (Shandong) Co.,Ltd**
No. 51 South Gongye Road, Jinan, Shandong Province, China

Related Directives and Annex: **2014/35/EU Low Voltage Directive (LVD)**
2014/32/EU Measuring Instruments Directives (MID)

Related Standards: **EN 61010-1:2010; EN 50470-1:2006**

Product(s): **BP Series Electronic Precision Balance**

Type(s)/Model(s): **BP1003B, BP1203B, BP2003B, BP3003B, BP4103B, BP5003B, BP10003, BP1003P, BP2003P, BP12002, BP21002, BP31002, BP50002, BP21001, BP31001, BP41001, BP51001, BP61001**

Classification: **Laboratory Equipment**

Examination Period: **December 15, 2018**

Date of Expiry: **December 14, 2023**

Review Result: **During the examination of the provided Technical Documentation, no Non-compliance according to the requirements of the Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/32/EU was detected.**

Year of DOC marking: 2018

Signed for and on behalf of
Company: **Biobase Bioindustry (Shandong) Co.,Ltd**

General Manager: *Robert Wang*

Document No: **SD-181215**





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

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. 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. γ -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. β 2-microglobulin detection kit (latex enhanced immunoturbidimetry)

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Biobase Biodustry (Shandong) Co., Ltd.

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)

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Annex IV

- 76. Immunoglobulin IgM detection kit (immunoturbidimetry)
- 77. α 1-acid glycoprotein detection kit (immunoturbidimetry)
- 78. α 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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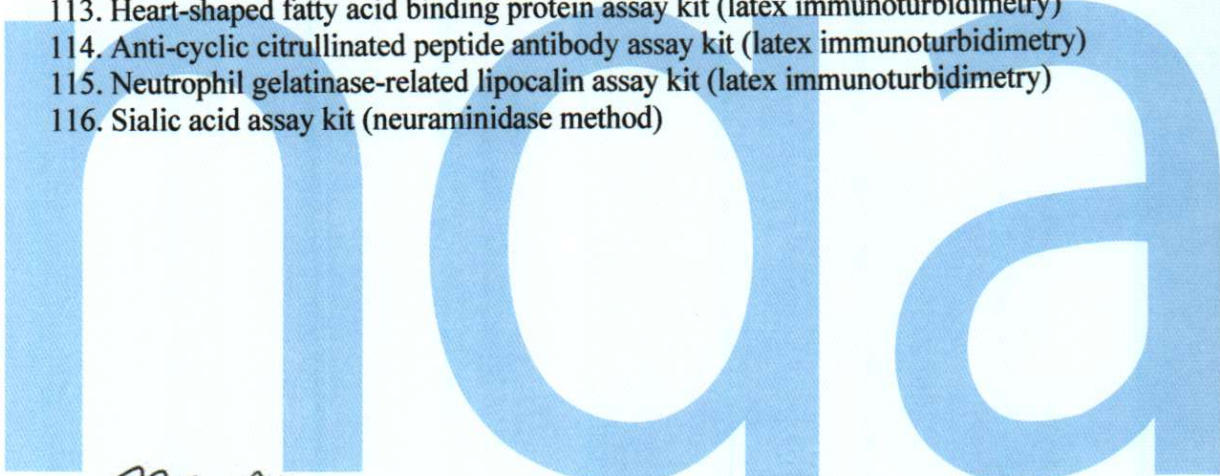




Biobase Biodustry (Shandong) Co., Ltd.

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. α 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. α 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)



M Combsley
 Managing Director

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