Laboratory Refrigerator

118L

238L

298L

628L/968L

Technical Parameters

Model		BPR-5V118	BPR-5V238	BPR-5V298	BPR-5V628	BPR-5V968
External Size(W*D*H) mm		500*550*1300	580*575*1810	620*575*1980	1220*630*1885	1220*860*1885
Capacity		118L	238L	298L	628L	968L
Temp. Range		2℃~8℃				
Temp. Accuracy		0.1℃				
Control System		Microprocessor Control, Large Screen LED Display				
Alarm		Audible and visual alarm for: High and low temperature, Power failure alarm, Door ajar,Thermostat failure				
Refrigeration Type		Forced air refrigeration system				
Refrigerant		R600a, CFC Free			R134a, CFC Free	
Condenser & Evaporator		Bundy tube condenser				
Defrost		Manual defrost Auto defrost				
Construction	Structure	Unibody Design & Mono-assembly foaming (Rigid polyurethane insulation material)			Unibody Design & Mono-assembly foaming (Polyurethane cyclopentane insulation material)	
	Internal Material	Embossed aluminum sheet			Spraying steel plate	
	External Material	Spraying steel plate				
Shelves		4 pcs	4pcs	5 pcs	10 pcs	
Door		Glass door with electric heating				
Consumption		162W	162W	189W	537W	
Power Supply		AC220V±10%, 50/60Hz(only for BPR-5V118) ,AC110/220V±10%, 50/60Hz				
Standard Accessories		LED Lamp,USB port, probe access port(BPR-5V628 & BPR-5V968)				
Optional Accessory		Temperature recorder,Temperature printer(USB port can not be selected at the same time), probe access port				
Package Size(W*D*H) mm		590*595*1380	670*650*1870	700*650*2030	1340*750*2100	1340*980*2100
Gross Weight		51kg	68kg	84kg	235kg	262kg

-86℃ Freezer


BDF-86V58


BDF-86V108


BDF-86V160

Technical Parameters

Model	BDF-86V58	BDF-86V108	BDF-86V160
External Size(W*D*H) mm	635*757*1212	700*730*1260	700*700*1580
Internal Size(W*D*H) mm	330*453*410	460*460*510	460*455*800
Capacity	58L	108L	158L
Type	Vertical		
Temp. Range	-40℃～-86℃		
Temp. Accuracy	0.1℃		
Control System	Microprocessor control, LED Digital Display		
Audible and Visual Alarm	High and low temperature alarm, sensor failure alarm, thermostat failure alarm, power failure alarm, door open alarm, ambient temperature alarm, condenser failure alarm, filter inspection alarm, abnormal voltage alarm, low battery alarm. (BDF-86V58) High and low temperature,sensor failure.(BDF-86V108 BDF-86V160)		
Alarm Method	Sound beeps and lights flash		
Refrigeration Type	Direct refrigeration	Optimized auto-cascade refrigerating system	
Refrigerant	R290 and R170	R404a and R23	
Compressor	1 set		
Condenser& Evaporator	Made of copper		
Foam Layer Thickness	150mm	120mm	
Construction / Internal Material	304 stainless steel		
External Material	Sprayed steel plate		
Door	Lockable door		
Caster	4 casters		
Chamber with Inner Door	1	2	3
Shelf	1pcs	1pcs	2pcs
Temp. Test Port	1, Φ25mm	1, Φ18mm	1, Φ18mm
Consumption	442W	520W	650W
Power Supply	AC110V/220V±10%, 50/60Hz		
Package Size (W*D*H) mm	730*845*1400	785*800*1430	800*780*1750
Gross Weight	155kg	133kg	155kg


338L

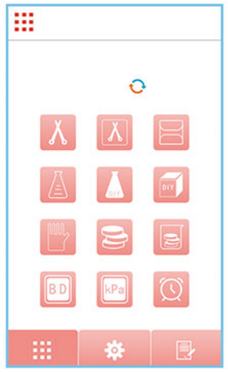

340L


408L

Technical Parameters

Model	BDF-86V338	BDF-86V340	BDF-86V408
External Size(W*D*H) mm	880*980*1940	875*980*1900	891*930*1945
Internal Size(W*D*H) mm	488*607*1140	488*607*1140	606*575*1180
Capacity	338L	340L	408L
Type	Vertical		
Temp. Range	-40~-86℃		
Temp. Accuracy	0.1℃		
Control System	Microprocessor control, LCD touch screen	Microprocessor control, LED display	
Audible and Visual Alarm	High and low temperature, Sensor failure, Door ajar, Power failure, Voltage abnormal, Ambient temperature abnormal, Low voltage, Filter blocking		
Refrigeration type	Optimized auto-cascade refrigerating system	Direct refrigeration	Optimized auto-cascade refrigerating system
Refrigerant	R290 and R170	R290 and R170	
Compressor	2 sets	1 set	
Condenser&Evaporator	Made of copper		
Construction / Structure	100mm ultra-thick foam layer	150mm ultra-thick foam layer	
Internal Material	SS 304		
External Material	Sprayed steel plate		
Door	Lockable door		
Caster	4 casters		
Chamber with Inner Door	2		
Shelf	3 pcs		
Temp. Test Port	1, φ25mm		
Consumption	870W	810W	890W
Power Supply	AC110V/220V±10%, 50/60Hz		
Standard Accessory	72 hours battery backup for power failure alarm, USB port		
Max. Optional Storage Racks	12*LD4×4	12*LD4×4	16*LD4×4
Max. Optional Boxes	192	192	256
Package Size (W*D*H) mm	940*1070*2130	935*1070*2130	955*955*2100
Gross Weight	305kg	283.5kg	291kg

Horizontal Pulse Vacuum Autoclave



Display

Chamber

Door

Introduction:

The pulse vacuum autoclave extracts vacuum and fills steam into the sterilization room for many times to make the sterilization chamber reach a certain vacuum degree, and then fills saturated steam to reach the set pressure and temperature, so as to achieve the purpose of sterilization of the sterilized substance.

Application:

It can be widely used in department of stomatology and ophthalmology, operating room and other medical institutions. It is suitable for all wrapped or unwrapped solid instrument, A-class cavity instrument (dental hand-pieces and endoscopes), implantable instrument, dressing fabric and rubber tubes, etc.

Features:

* Sterilization data output: standard micro printer, no need for separate external connection.
* 7-inch color LCD touch screen, which can display information such as temperature, pressure, operating status, fault alarm, cause analysis, and solutions at the same time.
* Strong vacuum drying system, the vacuum degree can be up to-92kpa, after drying, the residual humidity of device doesn't exceed 0.25%, the residual humidity of dressing doesn't exceed 1%.
* The air in the chamber is sterile and avoids re-contamination.
* Adopt quick-release side cover and top cover for easy maintenance and cleaning.
* Micro-controller programmable control technology.
* Full protective door cover, effectively prevent burns.
* The equipment adopt self-expanding sealing ring. sealing performance is more reliable and stable.
* The closing method adopts a multi-point pressing structure of the radiation rod, safe and reliable.
* The equipment is connected to the water source without manual replenishment. After the customer chooses the program, the equipment can complete the whole process from water injection to drying without human intervention.
* After the program is completed, the sound prompts sterilization to be completed.
* Built-in high speed steam generator, no external steam source, save time and effort.
* With mobile temperature sensor, can meet the special requirements of the laboratory.
* Pressure, mechanical and electronic three-layer safety interlock device, with over-temperature protection and over-pressure protection, can eliminate all safety risks.
* The quick release is the side cover and the top cover, which is convenient for equipment maintenance and cleaning.

Technical Parameters:

Model	BKQ-Z150H	BKQ-Z200H	BKQ-Z300H	BKQ-Z360H
Capacity	150L	200L	300L	360L
Max Designed Pressure	-0.1/0.3MPa			
Working Pressure	0.23MPa			
Working Temp.	105～134℃			
Noise	≤85dB			
Vacuum System	Water circulating vacuum pump			
Chamber Material	S30408			
Power Supply	380V/50Hz			
Consumption	20kVA			
External Size(W*D*H)mm	1190*940*1780	1400*940*1780	1570*1170*1980	1570*1170*1980
Chamber Size(mm)	φ500*780	φ500*1020	Φ650*980	Φ650*1130
Package Size(W*D*H)mm	1385*1110*2080	1585*1110*2080	1755*1330*2270	1755*1330*2270
Gross Weight(kg)	520	600	755	770

EC Declaration of Conformity

Manufacturer:

Jinan Biobase Biotech Co., Ltd.
OLABO Intelligent Manufacturing Industrial Park,
Ancheng Town, Pingyin County, Jinan City,
Shandong, China
The peoples republic of China

*whose single Authorized **EU**-Representative:*

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
SRN:DE-AR-000005110
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Freezer

Basic UDI-DI:

meet the provisions of Regulation (EU) 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation (EU) 2017/745. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Jinan Biobase Biotech Co., Ltd.
OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City,
Shandong,China

Jinan 2026.9
Place, date

Legally binding signature, Function

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	: Jinan Biobase Biotech Co., Ltd.
Company Address	: OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City, 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	: Refrigerator
Report No and Date	: EC.BIOBASE.20220607006-R-1
Product Brand/Model/Type	: BBR-4V86, BBR-4V106, BBR-4V116, BBR-4V136, BBR-4V166, BBR-4V186, BBR-4V216, BBR-4V236, BBR-4V286, BBR-4V296, BBR-4V326, BBR-4V356, BBR-4V386, BBR-4V466, BBR-4V536, BBR-4V586, BBR-4V626, BBR-4V736, BBR-4V856, BBR-4V966, BBR-4V1306, BPR-5V68, BPR-5V108, BPR-5V118, BPR-5V138, BPR-5V168, BPR-5V218, BPR-5V238, BPR-5V288S, BPR-5V298, BPR-5V328, BPR-5V358S, BPR-5V368, BPR-5V388, BPR-5V468, BPR-5V538, BPR-5V588, BPR-5V628, BPR-5V738, BPR-5V858, BPR-5V968, BPR-5V1308
Certificate Number	: M.2022.206.C74689
Initial Assessment Date	: 17.06.2022
Registration Date	: 20.06.2022
Reissue Date/No	: -
Expiry Date	: 19.06.2027

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)

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 www.udem.com.tr

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*	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
Descrizione dell'attrezzatura/insieme *Equipment/assemblies description*	Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave
Modelli *Models*	BKM-Series, BKQ-Series, BKS-Series
Fascicolo Tecnico n° *Technical file no.*	TPMJ202009043201
Dati tecnici *Technical Data*	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

CE 1282

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

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-CO82**

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

Timbro

Firma autorizzata
Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 06/09/2023

FINE DEL CERTIFICATO – *END OF CERTIFICATE*

ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

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-B200(H), BKQ-B300(H), BKQ-Z100(H), BKQ-Z150(H), BKQ-Z200(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: Robert Wang

Document No: BKMDD-190418

CE

ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

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 EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements 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

认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE

CERTIFICATE

This is to certify that the Quality Management System of

Biobase Disinfection (Shandong) Co., Ltd.

Business License Number: 91370181MA3C1M6N5G

Registered Address: Room 303, R&D Building, OLABO Intelligent Manufacturing Industrial Park, No. 1 Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

Audit Address: Workshop 11, Jidong Smart Manufacturing New Town, 2666 Puxue Road, Zhangqiu District, Jinan City, Shandong Province, China

applicable to

Production and sales of Vertical Autoclave, Table Top Autoclave, Horizontal Autoclave, Large Horizontal Autoclave

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ANSI National Accreditation Board ACCREDITED ISO/IEC 17021-1 MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

General Manager

Certificate Registration No：381220111R0M

Initial issue date：2022.08.08　　Issue date：2022.08.08　　Valid until: 2025.08.07

Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com