

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 din 03.07.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Biobase Bioindustry

Product: Autoclav

Model:

- 1. BKMZB**
- 2. BKM-Z45B**

Se anexează următoarele acte:

1. Certificat CE
2. Declarație de conformitate
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **03.07.2023**

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Biobase Bioindustry

Product: Autoclav

Model:

1. BKMZB

2. BKM-Z45B

Sunt autentice și corespund realității

Alexandru Grabazei, director

Semnătura _____

Data: **03.07.2023**

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

No. 51 South Gongye Road, Jinan, Shandong, China 250100

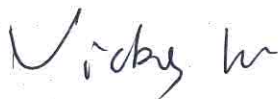
Fax: +86-531-81219804 Website: www.biobase.cc

Date: 18th. October. 2017.

Authorization

We, the undersigned Biobase Biodustry(Shandong) Co., Ltd., No. 51 South Gongye Road, Jinan, Shandong, China 250100, hereby appoint F.C.P.C. "DataControl" S.R.L., 20, Melestiu street, MD-2001, Chişinau, Republic of Moldova, to be official representative for registration, renewal, variation of registration, etc. at the responsible authorities of the Republic of Moldova.

Signature:



On behalf of Manufacturer: Biobase Biodustry(Shandong) Co., Ltd.

Title: Sales Supervisor

Seal:



BIOBASE

Biobase Disinfection (Shandong) Co.,Ltd.

ADD: Room 303, R&D Building,OLABO Intelligent Manufacturing Industrial Park,

No. 1, Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong

TEL: +86-531-81219803 FAX: +86-531-81219804

E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

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

Pressure Equipment Directive 2014/68/EU-Annex III have been taken as reference for these processes

Company Name: **Biobase Disinfection (Shandong) Co.,Ltd.**

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

Related Directives and Annex: Pressure Equipment Directive 2014/68/EU

Product(s): **Autoclave**

Type(s)/Model(s): BKM-Series, BKQ-Series, BK-Y-Series, BK-B-Series, HAS-Series, BKS-Y

Classification: **Laboratory Equipment**

Examination Period: **May 23, 2022**

Date of Expiry: **May 22, 2027**

Review Result: We, Biobase Disinfection (Shandong) Co.,Ltd. declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Pressure Equipment Directive 2014/68/EU was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: **Biobase Disinfection (Shandong) Co.,Ltd.**

RA Specialist:

Agen Wang

Document No: **BKSD-W22052302**



BIOBASE

ADD: BIOBASE Headquarters, No. 9 Gangxing Road, Pilot Free Trade Zone of Jinan, Shandong, China
TEL.: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

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

Medical Devices Regulation 2017/745 (EU) has been taken as reference for these processes

Company Name: Biobase Disinfection (Shandong) Co., Ltd.
BIOBASE Headquarters, No. 9 Gangxing
Road, Pilot Free Trade Zone of Jinan, Shandong, China

Examination Intent: Examination the completeness of the Technical Documentation
according to the requirements of Annex II excluding section 4
(Module H) of 2017/745 (EU)

Harmonised Standards: EN 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016

Product(s): Autoclave

Type(s)/Model(s): BKM-Z24B(III), BKM-Z45B(III), BKQ-Z100H

Classification: I (according to the classification rules of the MDR)

Examination Period: July 8, 2021

Date of Expiry: July 7, 2026

Review Result: We, Biobase Disinfection (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
2017/745 (EU) has been detected.

Year of DOC marking: 2021

Signed for and on behalf of

Company: Biobase Disinfection (Shandong) Co., Ltd

RA Specialist: 

Document No: MDR-Z21070807



BIOBASE

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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 documentation 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)

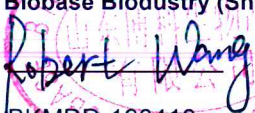
Relevant harmonised standards: see the attachment

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: 

Document No: **BKMDD-190418**



BIOBASE

ADD: No.51 South Gongye Road, Jinan, China250100
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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



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

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 Disinfection (Shandong) Co., Ltd.

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, 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

TPMJ202009043201

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

Questo certificato, compreso l'allegato, può essere riprodotto solo integralmente e senza alcuna variazione. Pagina 1 di 2
This certificate, annex included, may only be reproduced in its entirety and without any change. Page 1 of 2

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-C082**

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 Disinfection (Shandong) Co., Ltd.

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, 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 07/09/2020

Timbro



Firma autorizzata

Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 06/09/2023

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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+39 0516705141 +39 0516705156 ecm@entecerma.it www.entecerma.it

Table Top Autoclave Class B Series



Features:

- * **Built-in open type water tank**
The sterilizer adopts easy-clean open type water tank which can support repeated program running if fully injected with water.
- * **High-efficiency ultimate vacuum**
The sterilizer adopts high-efficiency low noise vacuum system which has excellent effects.
- * **Large LCD display for BKMZA/BKMZB**
The LCD screen can display temperature, pressure, time, operating status, failure warning and other information. It is convenient for customers to observe the sterilizer running status.
- * **Multiple program types**
The system has various programs that include packed items, unpacked items, BD testing program, vacuum testing program and drying function.
Custom program, rapid program and preheat function (for BKM-Z16B).
- * **Standard USB port for BKMZA/BKMZB**
Users can store the sterilization data with USB disk.
- * **Optional mini printer can be attached to record the process of sterilization.**

Technical Parameters:

Model	BKMZA (Previous name: BKM-Z18B)	BKMZB (Previous name: BKM-Z24B)
Capacity	18L	23L
Chamber Size(mm)	φ247*380	φ247*470
Sterilization Class	Class B	
Sterilization Temperature	121°C, 134°C	
Drying System	Vacuum drying system	
Display	LCD display	
Testing System	B&D Test Vacuum Test Helix Test	
Control Precision	Temperature: 1°C Pressure: 0.1bar	
Sterilization Data	BKM-Z16B: Printer(optional) BKMZA/BKMZB: USB(standard) and printer(optional)	
Safety System	Hand lock door Pressure lock system Relief valve in case of over pressure Pressure or temperature over load protection Alarm for system failure, finish reminding, water level warning	
Water Supply System	Build-in water tank easy to clean	
Water Tank Capacity	3.5L	
Water Consumption	0.16L~0.18L in one cycle	
Tray Holder	3 pcs SS trays on SS shelf	
Chamber	SUS304 Max working pressure: 2.3bar Min working pressure: -0.9bar Design temperature: 140°C	
Ambient Temp.	5~40°C	
Noise	<65dB	
Consumption	1950VA	1950VA
Power Supply	Standard: 220V±10%,50Hz/60Hz; Optional: 110V±10%,50Hz/60Hz. Wiring Method: Plug	
External Size(W*D*H)mm	495*600*410	495*700*410
Package Size(W*D*H)mm	610*810*590	610*810*590
Gross Weight(kg)	63	65

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

Table Top Autoclave Class B series

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 medical health care institution or R&D institution to make the sterilization for wrapped or unwrapped instrument, fabric, utensils, culture medium, unsealed liquid, etc.



Features:

* Brand-new operation interface

The LCD touch screen can display temperature, pressure, time, operating status, error and alarm information, etc.

There are different color changes in each stage of sterilization.

It is convenient for users to observe the sterilizer running status.

More importantly, the fault alarm not only displays the fault code, but also automatically displays the reason analysis and solution.

* Multiple safety protection devices

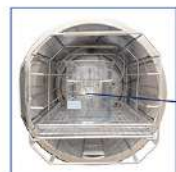
Automatic over-temperature protection device, multiple control and protection of evaporator, door safety interlock protection, double over-pressure protection device, etc.

* Mobile temperature sensor

The mobile temperature probe can directly detect the internal temperature of the liquid to ensure the sterilization effect of the liquid.

* Automatic door structure

Sterilizer adopts automatic door structure, which is fast and convenient to operate, effectively protects human body and prevents scalding.



* Vacuuming system

High efficiency vacuum extraction system, low working noise, over -90KPa extreme vacuum, fast extraction speed, good dryness, more complete sterilization

* A variety of programs

There are exposed procedures, packaging procedures, rubber procedures, dressing procedures, liquid procedures, liquid customization, solid customization, medium sterilization procedures, B&D testing, vacuum testing and media dissolution procedures.



* Other features

- A. Heating, sterilizing, exhausting and drying totally automatic.
- B. Chamber is heated by film heater, saving energy and time.
- C. 0.22μm high efficiency air filter, to avoid re-contamination of sterilized materials with filtration efficiency over 99.5%.
- D. Water filter in tank and chamber are quick to disassemble and easy for cleaning.
- E. Built-in stainless steel water tank, inner cycle of steam and water.
- F. Standard built-in printer.
- G. Standard USB port.

Technical Parameters:

Model	BKM-Z45B	BKM-Z60B	BKM-Z80B
Capacity	45L	60L	80L
Chamber Size(mm)	φ316*621	φ386*520	φ386*692
Design Pressure	-0.1/0.3MPa		
Sterilization Temperature	105℃~134℃		
Chamber Material	SUS304		
Ambient Temp.	5℃~40℃		
Consumption	5.8KW	6.2KW	
Power Supply	AC220V, 50Hz(Standard); AC110/220V, 60Hz(Optional); Wiring Method: Air switch		
External Size(W*D*H)mm	610*1020*610	805*940*700	805*1140*700
Package Size(W*D*H)mm	750*1200*880	960*1130*940	960*1330*940
Gross Weight(kg)	165	215	230

Note: It is applicable to the altitude below 3500 meters, and the parts need to be changed when the altitude is over 2000 meters.