



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This Certificate of Notification of production quality assurance is valid until 06/09/2023 and can be withdrawn if surveillance audits show that the quality system of production no longer complies with the provisions in Annex III module D1.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

Scadenza - Expiry date 06/09/2023



Firma autorizzata

Authorized signature

Amanda Payne
(Deputy Manager)

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
This certificate, annex included, may only be reproduced in its entirety and without any change. Page 2 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

质量管理体系 认证证书

证书号：HXC18921Q20254R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

质量管理体系符合

GB/T 19001-2016 / ISO 9001:2015 标准条款的要求

该体系认证所覆盖的范围

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
-------	-----	-------	-----	-------	-----

证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

www.hxccc.org

010-57146599

No. 0002277

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. : HXC18921Q20254R0M

Awarded to

Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Quality Management System of the above
organization has been assessed and Found to be in accordance with
the requirements of the standard:**

GB/T 19001-2016 / ISO 9001:2015

Scope of this management Certification

**R&D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
------------	-----------	-------------	-----------	------------	-----------

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802, 2nd Building, No. 6 South Street of Gulou, Changping District, Beijing City, China 010-57146599

No. 0002277

医疗器械质量管理体系 认证证书

证书号：HXC18921YL008R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

医疗器械质量管理体系符合

ISO 13485: 2016 标准要求

通过认证的范围为

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
-------	-----	-------	-----	-------	-----

证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

010-57146599

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certification No. : HXC18921YL008R0M

Awarded to
Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Medical Devices Quality Management Systems of the above
Organization has been assessed and Found to be in accordance with
the requirements of the standard:**

ISO 13485:2016

Scope of this management Certification

**R & D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
------------	-----------	-------------	-----------	------------	-----------

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802,2nd Building,No.6 South Street of Gulou,Changping District,Beijing City,China 010-57146599

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 BKM-Z18/24B**
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, custom program, rapid program, BD testing program, vacuum testing program, preheat program and drying program.
- * **Standard USB port for BKM-Z18/24B**
Users can store the sterilization data with USB disk.
- * **Optional mini printer can be attached to record the process of sterilization.**

Technical Parameters:

Model	BKM-Z16B	BKM-Z18B	BKM-Z24B
Capacity	16L	18L	24L
Chamber Size(mm)	φ230*360	φ247*360	φ247*470
Sterilization Class	Class B (according to GB0646)		
Sterilization Temperature	121℃, 134℃		
Special Program	HIV, HBV long-sterilization program	/	
Drying System	Vacuum drying system		
Display	LED display	LCD display	
Testing System	B&D Test		
	Vacuum Test		
	Helix Test		
Control Precision	Temperature: 1℃ Pressure: 0.1bar		
Sterilization Data	BKM-Z16B: Printer(optional) BKM-Z18B/BKM-Z24B: 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	2L	4L	
Water Consumption	0.4L in one cycle	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℃		
Ambient Temp.	5~40℃		
Noise	<50dB		
Consumption	1800W	1950W	1950W
Power Supply	AC110/220V±10%, 50/60Hz		
External Size(W*D*H)mm	445*550*395	495*600*410	495*700*410
Package Size(W*D*H)mm	550*670*500	610*810*590	610*810*590
Gross Weight(kg)	47	63	65

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