

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 Morina

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

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
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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
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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
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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



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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
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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
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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 Low Speed Centrifuge

Features:

- * Brushless motor.
- * Stainless steel chamber.
- * Can store 20 operation procedures.



Technical Parameters:

	BKC-TL4	BKC-TL4IV	BKC-TL5II	BKC-TL5VII	BKC-TL6	BKC-TL6II
Model	BKC-TL4	BKC-TL4IV	BKC-TL5II	BKC-TL5VII	BKC-TL6	BKC-TL6II
Max. Capacity	8*20ml	6*50ml	4*100ml	6*50ml	4*250ml	4*100ml
Max. Speed	4000rpm	4000rpm	5000rpm	5000rpm	6000rpm	6000rpm
Max. RCF	2200xg	2200xg	4420xg	4020xg	5140xg	5140xg
Timing Range	0~99h59min	1~60min	0~99h59min	0~99min	0~99h59min	0~99h59min
Speed Precision	±30rpm	/	±50rpm	±30rpm	±50rpm	±50rpm
Noise	≤60dB	≤65dB	≤58dB	≤58dB	≤65dB	≤65dB
Consumption	100W	180W	350W	300W	500W	500W
Power Supply	AC220V, 50/60Hz					
External Size(W*D*H)mm	380*260*310	395*340*305	500*400*300	330*295*255	600*540*360	600*540*360
Package Size(W*D*H)mm	550*410*510	500*400*330	700*600*500	480*445*455	800*740*560	800*740*560
Net/Gross Weight(kg)	18/33	20/22	25/44	20/28	35/50	35/50

Rotor for BKC-TL4IV/TL5VII:

No.	Rotor	BKC-TL4IV Capacity	Speed(rpm)	RCF(xg)	BKC-TL5VII Capacity	Speed(rpm)	RCF(xg)	Tube(mm)
No.1	Angle Rotor	18*10/7ml	4000	2200	18*10/7ml	5000	4020	Φ16*120
No.2		24*10/7ml			24*10/7ml			
No.3		12*15/10ml			12*15/10ml			
No.4		12*20/15ml			12*20/15ml			
No.5		6*50ml			6*50ml			

Rotor for BKC-TL5II/TL6/TL6II:

Rotor	BKC-TL5II Capacity	Speed(rpm)	RCF(xg)	BKC-TL6 Capacity	Speed(rpm)	RCF(xg)	BKC-TL6II Capacity	Speed(rpm)	RCF(xg)
Angle Rotor	12*15ml	5000	3580	12*10ml	6000	5140	12*10ml	6000	5140
	24*10ml	4000	2600						
Swing Bucket Rotor	4*50ml	5000	4420	16*15ml	5000	4400	/	/	/
	4*100ml	4000	2100	24*10ml	4000	2810	/	/	/
	8*50ml	/	/	4*250ml	4000	3290	/	/	/
	24*5ml (vacuum tube)	4000	2950	/	/	/	4*50ml	5000	4600
	16*15ml	4000	2950	/	/	/	4*100ml	5000	4800
	32*15ml	/	/	/	/	/	8*50ml	4000	2810
	32*10ml	/	/	/	/	/	32* 0ml	4000	2810
	48*5ml/2ml (vacuum tube)	/	/	/	/	/	48*5ml/2ml (Vacuum tube)	4000	2940
	76*5ml/2ml (vacuum tube)	/	/	/	/	/	76*5ml/2ml (Vacuum tube)	4000	3100
	Microplate	/	/	/	/	/	2*2*96 (well)	4000	2360

Table Top Low Speed Large Capacity Centrifuge



Technical Parameters:

Model	BKC-TL5LII
Max. Capacity	4*750ml
Max. Speed	5500rpm
Max. RCF	5310xg
Speed Accuracy	±20rpm
Timing Range	0~99h59min59s
Noise	≤58dB
Consumption	2.5KW
Power Supply	AC220V, 50Hz
External Size(W*D*H) mm	800*700*400
Package Size(W*D*H) mm	950*850*600
Net Weight(kg)	110
Gross Weight(kg)	135

Features:

- * Programmable microprocessor control(AC brushless motor)
- * **LCD display:** speed, RCF, time, conversion of RPM/RCF
- * External cold-rolled steel with powder coating, stainless steel centrifugal chamber and lid
- * Fan-forced air circulation system for fast recovery of temperature
- * 10 procedures of adjustable speed from levels 0 to 9 and 40 kinds of self-defining modes
- * Electronic lock lid and interlock safety system. Auto lock rotor system
- * **Alarm:** lid open, imbalance, over speed and rotor mounting abnormally
- * **Functions:** RCF selection, quick run, automatic rotor recognition and backup. Electronic imbalance detection, dynamic electric brake system, inching function, short-spin function

Rotor:

No.	Rotor	Speed(rpm)	RCF(xg)	Capacity	No.	Rotor	Speed(rpm)	RCF(xg)	Capacity
No.1	Swing Rotor	5000	4390	4*100ml	No.2	Adapter	4000	3500	4*2*50ml
	Adapter	4000	3500	4*2*100ml		Swing rotor	4000	3580	4*100ml
				4*4*10ml	4*500ml				
				4*6*10ml	4*12*7ml				
				4*8*10ml	4*12*10ml				
				4*4*15ml	4*8*15ml				
				4*6*15ml	4*4*50ml				
				4*8*15ml	4*2*100ml				
				4*50ml	4*250ml				
	4000	3500	4*2*50ml	No.4	Swing rotor	4000	3580	4*750ml	
No.2	Swing Rotor	4000	3500	4*250ml	No.5	Swing rotor	4000	2800	4*15*5/7ml
	Adapter	4000	3500	4*8*7/5ml	No.6	Swing rotor	4000	2800	4*18*5/7ml
				4*8*10ml	No.7	Swing rotor	4000	2800	4*24*5/7ml
				4*8*15ml	No.8	Swing rotor	4000	2800	4*30*5/7ml