





Elisa Microplate Reader BK-EL10C

Features:

- 1. 8-channel vertical optical system.
- ②. Reading speed of 7 seconds.
- 3. 10.1-inch large touch screen with visual layout function.
- 4. Hardware: ARM architecture high-performance low-power
- (5). Processor, with ADI high-precision AD conversion chip, the measurement is more accurate and stable.
- ⑤. Software: Self-developed core algorithm, with independent intellectual property rights, flexible use of multiple calculation methods.



Parameters:

Model	BK-EL10C	
Measurement Channel	Vertical 8 optical channels	
Wavelength Range	400~800 nm	
Filter	Standard 4 wavelengths of 405, 450, 492, 630nm;	
	can be installed up to 10 filters (optional)	
Reading Range	0.000~4.000 Abs	
Linear Range	0.000~3.000 Abs	
Repeatability	CV≤1.0%	
Stability	≤±0.003Abs	
Vibration Plate Function	3 kinds of vibration plate function, adjustable 0~255 seconds	
Display	10.1 Inch Large Touch Screen	
Power Supply	AC110/220V, 60/50Hz	
Net Weight	11kg	
Gross Weight	13kg	
Instrument Size (W*D*H)	320*450*300mm	
Packing Size (W*D*H)	535*395*395mm	

Elisa Microplate Washer

Feature:

- * Microcomputer control, automatically complete the plate washing operation.
- * The liquid level sensing function automatically detects the liquid level, and automatically alarms when the cleaning liquid is insufficient and the waste liquid is overflowing.
- * The user-friendly operating system allows users to customize the plate type, set the number of washes, the amount of wash solution, the way to wash the plate, the suction point, the soaking and shaking time and other parameters.
- * The wash head is self-balancing, has two-point aspiration, and performs bottom flushing.
- * 2 kinds of Automatic washing, Soaking and Shaking, to reduce the interference adsorption during the reaction; time adjustable.



BK-9613



BK-9622

Parameters:

Model	BK-9622	BK-9613
Cleaning Head	8 channels and 12 channels	96 pins, single row controllable
MicroplateTypes	Four kinds, flat bottom, U bottom, V bottom, round bottom	
Average Residue	<1µl(per hole)	<0.7µI(per hole)
Liquid Suction Time	0.1~999.9 seconds adjustable, with an interval of 0.1 seconds	
Line Flush Time	0~240 seconds, adjustable	
Washing Programs	Up to 200 programs	
Display	7-inch touch display	
Liquid Injection Channels	3 (2 types of lotion and 1 type of distilled water)	
Cleaning Needle Position	6 types (horizontal, left, middle, right, bottom, hole spacing)	
Consumption	80W	350W
Power Supply	AC220V±10%, 50/60Hz; 110±10%, 60Hz	
Packing size(W*D*H):	690*490*400mm	740*675*562mm
Gross Weight	22kg	42kg

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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









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

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.









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

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有效日期: **2024 年 7 月 4 日** 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)

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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)

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Labelling

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









EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

Biobase Biodustry(Shandong) Co.,Ltd.

NO.9 Gangxing Road , High-Tech Zone ,Jinan City ,

Shandong Province, China

Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany DIMDI: DE/0000047791 SRN: DE-AR-000005110 Lin Sun

Tel: 0049- 1715605732 E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Microplate Washer

BK-9613, BK-9621, BK-9622, OLB-12X, OLB-96X, etc..

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

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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

Biobase Biodustry(Shandong) Co.,Ltd.

NO.9 Gangxing Road , High-Tech Zone ,Jinan City , Shandong Province, China

Jinan. 2021.09.27

Place, date

Legally binding signature, Function

Xi meny Zhang



Registration Notification

Reference Number: JH-ERA-MDR-21287V00 Effective Period: 2021.09.17-2024.05.26

This notification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is notice that, According to Medical Device Regulation (EU) 2017/745(MDR), we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Biobase Biodustry(Shandong) Co., Ltd.

Address: NO.9 Gangxing Road , High-Tech Zone ,Jinan City , Shandong Province, China

The Manufacturer declared that the Medical Device complies with de Directive including all essential requirements.

According to Medical Device Regulation (EU) 2017/745(MDR), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's Medical Devices and has allocated registration numbers shown in:

Microplate Washer, UMDN code: 17-489
Registration Number: DE/CA20/00181460

Medical Centrifuge, UMDN code: 10-778
Registration Number: DE/CA20/00181461

Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

For and on behalf of

Luxus Lebenswelt GmbH

Kochstr. 1, 47877, Willich, Germany info.m@luxuslw.de

LUXUS LEBENSWELT GMBH
Kochstr.1, 47877 Willich, Germany

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Only used for EU Representative Agreements