

Semi-auto Chemistry Analyzer

BIOBASE-Silver



Features:

- ①. Easy operation by one button.
- ②. End point, kinetic, fixed time, rate, etc.
- ③. Filter wavelength: 340/405/450/510/546/578/630nm, 2 more open filter positions, others on request.
- ④. With 20 incubating positions.
- ⑤. Large Memory to store 144 test programs and 5600 testing results.
- ⑥. Excellent Q.C function, Q.C chart can be stored, displayed and printed.
- ⑦. 37°C temperature in flow cell and incubating.
- ⑧. Real time graph can be displayed and printed.

Parameters:

Model	BIOBASE-Silver
Reading cuvette	Quartz cuvette; Both through cell and direct reading cuvette
Incubating positions	20 incubating positions
Photometric System	Light source: 6V, 10W long life halogen lamp
	Filters: 340/405/450/510/546/578/630nm, 2 more open filter positions
	Wavelength accuracy: ± 2 nm
Measuring System	Measuring range: 0~3.500O.D.
	Photometric linearity: $\pm 2\%$ from 0 to 2.500 O.D.
	Photometric accuracy: $\pm 2\%$ from 0 to 2.500 O.D.
	Drift<0.005 O.D.
Incubator Temperature	R.T. 25°C, 30°C, 37°C
Control	Precision: $\pm 0.1^\circ\text{C}$
Display	Touch Screen
Printer	Built-in thermal printer
Interface	RS-232, USB
Power Supply	AC110/220V $\pm 10\%$, 60/50Hz
External Size(W*D*H)	400*380*200mm
Packing Size(W*D*H)	500*530*350mm
Gross Weight	12kg

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



张建国



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.hxcc.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 side for accurate information.



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）

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/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。
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初次获证日期：2021 年 7 月 5 日

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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

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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)**

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张建国



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

Declaration of Conformity

Manufacturer: Biobase Biodustry(Shandong) Co.,Ltd.
NO.9 Gangxing Road , High-Tech Zone ,Jinan City ,
Shandong Province, China

SRN:
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

Product Name: Semi-auto Chemistry Analyzer

Classification (IVDR, Annex VIII): Class A, Rule 5.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the
Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products
meet the transposition into national law, the provisions of the following EU Regulation
and Standards. All supporting documentations are retained under the premises of the
manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April
2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and
Commission Decision 2010/227/EU.

Applied standards, common specification, guidance:

ISO 14971:2019, EN ISO 18113-1:2011, EN 13612:2002/AC:2002,EN
1041:2008+A1:2013, EN ISO 15223-1:2016, IEC 61010-1:2010+AMD1:2016 CSV,
IEC 61326-1:2012, IEC 61326-2-6: 2012.

Signature: Xu Yong

Date: 2021-9-21

Title: GM

Position: Jinan



Declaration of Conformity

Manufacturer: Biobase Bioindustry(Shandong) Co.,Ltd.
NO.9 Gangxing Road , High-Tech Zone ,Jinan City ,
Shandong Province, China

SRN:
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

Product Name: Automatic Chemistry Analyzer
BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280,
BK-200, BK-200mini.etc.

Classification (IVDR, Annex VIII): Class A, Rule 5.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the
Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products
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1041:2008+A1:2013, EN ISO 15223-1:2016, IEC 61010-1:2010+AMD1:2016 CSV,
IEC 61326-1:2012, IEC 61326-2-6: 2012.

Signature: *Lin Sun*

Date: 2024.9.27

Title: GM

Position: *Lin Sun*

