

CELAB®

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CERTIFICATE

Certificate Number **UCN** : **802497389091**

Job : J27439

Date of Issue : 2019-09-09

Certificate valid up to : 2023-09-08

Brand Name : See Label

Type : Automatic chemistry analyzer

Model N : BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280, BK-200, BK-200mini

Manufacturer : Biobase Biodustry(Shandong) Co., Ltd

Address : Biobase Industry Park, Crossing of Jingshi East Road and Mingbu Road,
Mingshui Economic Development Zone, Zhangqiu, Jinan City Shandong Province, China

Standard Used : EN 60601-1:2006+A1:2013


Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:

93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity	✓ OK
Test report reference : ESC-BBBS-2019-09-1C	
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

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Massimiliano Bertoldi
General Manager – CELAB
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General Manager – CELAB
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REGISTRATION NO. 04719Q10000898

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Jinan Biobase Biotech Co., Ltd.

Registered Address: OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City, Shandong

Manufacturing Address: North Side of Jiwang Road, Mingshui Economic Development District, Zhangqiu, Jinan City; OLABO Intelligent Manufacturing Industrial Park, Ancheng Town, Pingyin County, Jinan City, Shandong

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of biological safety cabinet; Class I Biosafety Cabinet; carbon dioxide incubator; low temperature freezer; laminar flow cabinet; biological isolation chamber; centrifuge; fume hood; PCR cabinet; dispensing booth.

Date of issue: July 22, 2019

Date of expiry: July 21, 2022

Date of change: July 06, 2021

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

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
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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