

# 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)**

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| 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](http://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

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