



LOW VOLTAGE DIRECTIVE, ELECTROMAGNETIC COMPATIBILITY DIRECTIVE ATTESTATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully.

2014/30/EU Electromagnetic Compatibility Directive and 2014/ 35/EU Low Voltage Directive has been taken as references for these processes.

Company Name : Jinan Biobase Biotech Co., Ltd.

Company Address : North Side of Jiwang Road, Mingshui Economic Development District, Zhangqiu, Jinan City, China

Related Directives and Annex : 2014/35/EU Low Voltage Directive /Annex III
2014/30/EU Electromagnetic Compatibility Directive /Annex II

Related Standards : EN 61010-1:2010/A1:2019, EN IEC 61326-1:2021
EN IEC 61326-2-2:2021, EN IEC 61000-3-2:2019+A1:2021
EN 61000-3-3:2013+A1:2019+A2:2021

Product Name : Freezer

Report No and Date : LVD- PTC23061205501S-LD01, EMC- PTC23061205501E-EM01

Product Brand/Model/Type : BDF-25V100, BDF-25V208, BDF-25V270, BDF-25V350, BDF-40V58, BDF-40V90, BDF-40V208, BDF-40V268, BDF-40V268C0, BDF-40V328, BDF-40V362, BDF-40V368, BDF-25V368D, BDF-30V368D, BDF-40V368D, BDF-25V528D, BDF-30V528D, BDF-40V528, BDF-40V398, BDF-40V936, BDF-40V608, BDF-40V708, BDF-40V808, BDF-40V528D, BDF-25H110, BDF-25H210, BDF-25H226, BDF-25H310, BDF-25H360, BDF-40H105, BDF-40H205, BDF-40H305, BDF-40H485, BDF-40H110, BDF-40H210, BDF-40H310, BDF-25V400P, BDF-25V936, BDF-40V608, BDF-40V708, BDF-40V808, BDF-25H305, BDF-25V268, BDF-25V368, BDF-25V265, BDF-25V400, BDF-25V400P, BDF-25V300RF, BDF-25V100, BDF-25V936, BDF-60V65, BDF-86V65, BDF-86H60, BDF-86H128, BDF-86H388, BDF-86H488, BDF-86V168, BDF-86V348, BDF-86V168T, BDF-86V348T, BDF-86V418T, BDF-86V608T, BDF-86V168DT, BDF-86V348DT, BDF-150H58, BDF-150H128, BDF-60V30, BDF-60V608, BDF-60V708, BDF-60V808, BDF-60V938, BDF-86V58, BDF-80V30, BDF-86V28, BDF-80V30, BDF-60H58, BDF-60H118A, BDF-60H218, BDF-60H318, BDF-60H458, BDF-60V58, BDF-60V108, BDF-60V158, BDF-60V398, BDF-60V30, BDF-60V608, BDF-60V708, BDF-60V808, BDF-60V938, BDF-86V108, BDF-86V340, BDF-86V588, BDF-86V160, BDF-86V338, BDF-86V408, BDF-86V728, BDF-86V838, BDF-86V58, BDF-86V28, BRF-25V318, BRF-40V318, BRF-25V368, BRF-40V368, BRF-25V450, BRF-40V450, BRF-25V535, BRF-40V535, BDF-25V328, BDF-25H485, BDF-86V158, BDF-86V180, BDF-86H105, BDF-86V588E, BDF-86V735, BDF-86V938

Certificate Number : M.2023.206.C87490

Initial Assessment Date : 06.07.2023

Registration Date : 07.07.2023

Reissue Date/No : -

Expiry Date : 06.07.2028

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Registration No. 04722Q10000272

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

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; Workshop No.7, Medical Device Industrial Park, Juancheng County, Heze City, Shandong Province**

Operates a Quality Management System which complies with the requirements of:

GB/T 42061-2022 idt ISO 13485:2016

For the following scope:

The design, development, manufacture, distribution and service of Biological Safety Cabinet, Laminar Flow Cabinet, Biological Isolation Chamber, Air Purifier, Fume Hood, PCR Cabinet, Dispensing Booth, Freezer, Laboratory Refrigerator, Blood Bank Refrigerator.

Date of issue: **July 22, 2022**

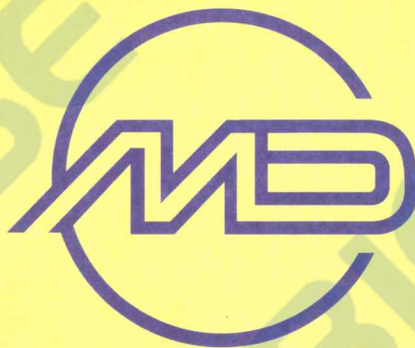
Date of expiry: **July 21, 2025**

Date of change: **June 04, 2023**

General manager:

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





Registration No. 04722Q10272R2M

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Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

The design, development, manufacture, distribution and service of Biological Safety Cabinet, Laminar Flow Cabinet, Biological Isolation Chamber, Air Purifier, Fume Hood, PCR Cabinet, Dispensing Booth, Freezer, Laboratory Refrigerator, Blood Bank Refrigerator.

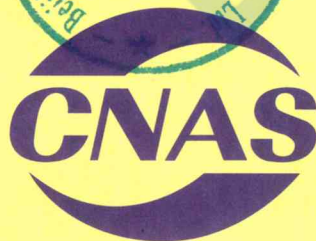
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Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993