

BIOBASE

ADD: BIOBASE Headquarters, No. 9 Gangxing Road, Pilot Free Trade Zone of Jinan, Shandong, China
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

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

Medical Devices Regulation 2017/745 (EU) has been taken as reference for these processes

Company Name: **Biobase Biodustry (Shandong) Co., Ltd.**
BIOBASE Headquarters, No. 9 Gangxing
Road, Pilot Free Trade Zone of Jinan, Shandong, China

Examination Intent: Examination the completeness of the Technical Documentation
according to the requirements of Annex II excluding section 4
(Module H) of 2017/745 (EU)

Harmonised Standards: **EN ISO 13485:2016; EN 60601-1-2:2015; EN 60601-1-6:2010**

Product(s): **Infrared Thermometer**

Type(s)/Model(s): **AET-R1B1, BK-HE-I**

Classification: **I (according to the classification rules of the MDR)**

Examination Period: **June 30, 2021**

Date of Expiry: **June 29, 2026**

Review Result: We, Biobase Biodustry (Shandong) Co., Ltd, declare that during the self-
testing and performance evaluation, no Non-compliance according to
the requirements of Annex II excluding section 4 (Module H) of 2017/745
(EU) has been detected.

Year of DOC marking: **2021**

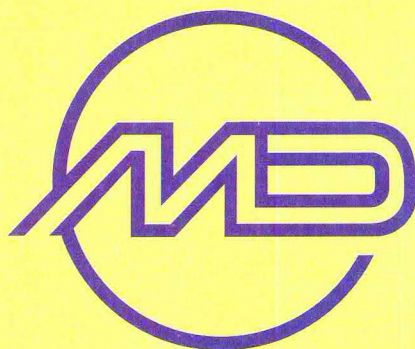
Signed for and on behalf of

Company: **Biobase Biodustry (Shandong) Co., Ltd.**

RA Specialist: Zona Qu

Document No: **MDR-Z21063001**





REGISTRATION NO. 04719Q10781R1M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Jinan Biobase Biotech Co., Ltd.

Registered Address: Floor 5, Science and Technology Incubator Building, No. 6
Lanxiangzhong Road, Tianqiao District, Jinan City

Postcode: 250000

Manufacturing Address: No. 51 South Gongye Road, Jinan City; North Side of
Jiawang Road, Mingshui Economic Development District, Zhangqiu, Jinan City

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

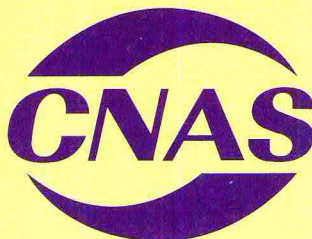
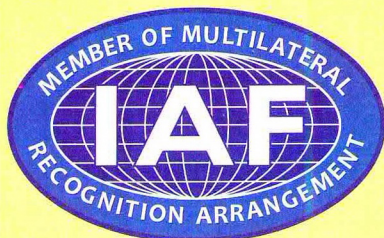
The Design, Development, Production and Service of biological safety cabinet;
BYKG series air segregation equipment; QP series carbon dioxide incubator; BDF
series freezer; laminar flow cabinet; centrifuge; fume hood; PCR cabinet; dispensing
booth.

Date of issue: July 22, 2019

Date of expiry: July 21, 2022

General Manager:

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



中国认可
国际互认
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CNAS C047-M

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (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