BIOBASE

Jinan Biobase Biotech Co., Ltd.
ADD: OLABO Intelligent Manufacturing Industrial Park,Ancheng Town,Pingyin County, Jinan CityShandong)
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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:	**Jinan Biobase Biotech Co., Ltd.** OLABO Intelligent Manufacturing Industrial Park,Ancheng Town,Pingyin County, Jinan CityShandong
Related Directives and Annex:	Examination the completeness of the Technical Documentation according to the requirements of 2017/745 (EU)
Related Standards:	**EN 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016**
Product(s):	**CO_2 Incubator**
Type(s)/Model(s):	BJPX-C80
Classification:	I (according to the classification rules of the MDR)
Examination Period:	April 2, 2022
Date of Expiry:	April 1, 2027
Review Result:	We, Jinan Biobase Biotech Co., Ltd., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of Medical Devices Regulation 2017/745/EU has been detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: **Jinan Biobase Biotech Co., Ltd.**

RA Specialist: Ajen Wang

Document No: MRD-A22040203

CE

Digitally signed by Grabazei Alexandru
Date: 2025.04.15 09:52:59 EEST
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EC DECLARATION OF CONFORMITY

We, **Biobase Biodustry (Shandong) Co., Ltd,**
No. 51 South Gongye Road, Jinan City, Shandong Province, P.R. China

herewith declare that the blow mentioned product meets the provisions of the **Council Directive 93/42/EEC** for Medical Device Directive (MDD). All supporting documention is retained under these premises and/or the premises of manufacture's subcontractors.

Product Name: **Pressure Steam Autoclave**

Model: **BKM-Z18N, BKM-Z24N, BKM-Z16B, BKM-Z18B, BKM-Z24B, BKM-Z18B(III), BKM-Z24B(III), BKM-Z45B(III), BKM-Z60B(III), BKM-Z80B(III), BKM-Z24S, BKM-Z45S, BKM-Z80S, BKQ-Z30I, BKQ-Z50I, BKQ-Z75I, BKQ-Z100I, BKQ-B50(II), BKQ-B75(II), BKQ-B100(II), BKQ-B120(II), BKQ-B150(II), BKQ-B200(II), BKQ-B50V, BKQ-B75V, BKQ-H150, BKQ-H200, BKQ-H300, BKQ-H400, BKQ-H500, BKQ-B100(H), BKQ-B150(H), BKQ-B200(H), BKQ-B300(H), BKQ-Z100(H), BKQ-Z150(H), BKQ-Z200(H), BKQ-Z300(H)**

Classification: **IIb** (according to classification rules in Annex IX of 93/42/EEC)

GMDN: **Sterilizer, moist heat, fluid / 41450**

Conformity Assessment Rout: Annex II excluding section 4(Module H)

Relevant harmonised standards: see the attachment

This DECLARATION OF CONFORMITY is valid in connection with the release document for the respective serial of produced devices.

The DECLARATION OF CONFORMITY is only valid in connection with a batch specific Certificate of compliance for the above products concerned bearing the CE mark.

Date of CE marking: April 18, 2019

Signed for and on behalf of
Company: **Biobase Biodustry (Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: BKMDD-190418

CE

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Attachment

For
the Relevant Harmonised Standards

Standard	Title
EN 13060:2014	Small steam sterilizers
EN 14180:2003+A2:2009	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
EN ISO 13485:2016 EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

REGISTRATION NO. 04722Q10000272

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

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; CO_2 Incubator; Low Temperature Freezer; Laminar Flow Cabinet; Biological Isolation Chamber; Fume Hood; PCR Cabinet; Dispensing Booth.

Date of issue: July 22,2022

Date of expiry: July 21,2025

General Manager: 李朝晖

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

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