BIOBASE

ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

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

Digitally signed by Grabazei Alexandru
Date: 2024.04.12 11:57:18 EEST
Reason: MoldSign Signature
Location: Moldova

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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

Garanzia di Qualità del Processo di Produzione

Quality Assurance of the Production Process

n. ECM PED-D1 2020-CO82

Rilasciato i sensi della Direttiva 2014/68/UE – Allegato III

Issued according to 2014/68/EU Directive – Annex III

Fabbricante
Manufacturer

Ragione Sociale *Company Name*	Biobase Disinfection (Shandong) Co., Ltd.
Sede Legale *Registered office*	C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China
Sede Operativa *Headquarters*	C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China
Descrizione dell'attrezzatura/insieme *Equipment/assemblies description*	Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave
Modelli *Models*	BKM-Series, BKQ-Series, BKS-Series
Fascicolo Tecnico n° *Technical file no.*	TPMJ202009043201
Dati tecnici *Technical Data*	V: 1.8 to 352L PS: -1 to 3bar Fluid Group: 2 Temperature Range: 0 to 150°C

Questo certificato è basato sul rapporto di verifica ispettiva n. PTPRD01_CO82 emesso il 04/09/2020.
I risultati delle verifiche periodiche del sistema qualità sono parte integrante di questa notifica.
Questo Certificato di Notifica della garanzia di qualità della produzione è valido fino al 06/09/2023 e può essere ritirato se dalle verifiche ispettive di sorveglianza risulta che il sistema di qualità della produzione non è più conforme a quanto previsto dall'allegato III modulo D1.
In accordo con quanto previsto nell'Allegato III modulo D1 della Direttiva 2014/68/UE la marcatura CE sul prodotto deve essere seguita dal n. 1282 che identifica ECM come l'Organismo Notificato incaricato della sorveglianza della produzione.

This certificate is based on the audit report no. PTPRD01_CO82 issued on 04/09/2020.
The results of periodic audits of the quality system is an integral part of this notification.
This Certificate of Notification of production quality assurance is valid until 06/09/2023 and can be withdrawn if surveillance audits show that the quality system of production no longer complies with the provisions in Annex III module D1.
In accordance with the Annex III module D1 of Directive 2014/68/EU the CE marking must be followed by n. 1282 that identifies ECM as Notified Body responsible for supervising the production.

Esempio di marcatura
Marking example

CE 1282

Data di prima emissione
Date of first issue 07/09/2020

☐ Estensione - Extension ☐ Rinnovo - Renewal

Valsamoggia (BO)
Data - *Date* 07/09/2020

Timbro

Firma autorizzata
Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza - *Expiry date* 06/09/2023

Ente Certificazione Macchine srl
Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)
☎ +39 0516705141 🖷 +39 0516705156 ✉ ecm@entecerma.it www.entecerma.it

Allegato al Certificato n.

Appendix to Certificate no.

n. **ECM PED-D1 2020-CO82**

Rilasciato i sensi della Direttiva 2014/68/UE – Allegato III

Issued according to 2014/68/EU Directive – Annex III

Richiedente
Applicant

Ragione Sociale *Company Name*	Biobase Disinfection (Shandong) Co., Ltd.
Sede Legale *Registered office*	C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China
Sede Operativa *Headquarters*	C4-404, Xing'an Community, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China
Apparecchio/insieme *Equipment/assembly*	Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave

Apparecchio soggetto a sorveglianza
Equipment subjected to surveillance

BKM-Series, BKQ-Series, BKS-Series

Valsamoggia (BO)

Data - *Date* 07/09/2020

Timbro

Firma autorizzata
Authorized signature

Amanda Payne
(Deputy Manager)

Scadenza- Expiry date 06/09/2023

FINE DEL CERTIFICATO – *END OF CERTIFICATE*

BIOBASE

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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 Directive 93/42/EEC has been taken as reference for these processes

Company Name:	**Biobase Biodustry (Shandong) Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Examination Intent:	Examination the completeness of the Technical Documentation according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC
Product(s):	**Sterilizer**
Type(s)/Model(s):	BKM-Series, BKQ-Series
Classification:	IIb
Harmonized Standards Applied:	All requirements of the appropriate EU directive(s) should be met.
Examination Period:	December 24, 2017
Date of Expiry:	December 23, 2022
Review Result:	During the examination of the provided Technical Documentation, no Non-compliance according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC has been detected.

Year of DOC marking: **2017**

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

General Manager: Robert Wang

Document No: MDD-17081110

BIODUSTRY (SHANDONG) CO., LTD 山东博科生物产业有限公司

CE

认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE

CERTIFICATE

This is to certify that the Quality Management System of

Biobase Disinfection (Shandong) Co., Ltd.

Business License Number: 91370181MA3C1M6N5G

Registered Address: Room 303, R&D Building, OLABO Intelligent Manufacturing Industrial Park, No. 1 Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

Audit Address: Workshop 11, Jidong Smart Manufacturing New Town, 2666 Puxue Road, Zhangqiu District, Jinan City, Shandong Province, China

applicable to

Production and sales of Vertical Autoclave, Table Top Autoclave, Horizontal Autoclave, Large Horizontal Autoclave

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ANSI National Accreditation Board ACCREDITED ISO/IEC 17021-1 MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

General Manager

Certificate Registration No：381220111R0M

Initial issue date：2022.08.08　　Issue date：2022.08.08　　Valid until: 2025.08.07

Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com