

BIOBASE

BIOBASE BIODUSTRY (SHANDONG) CO., LTD
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EC DECLARATION OF CONFORMITY ECM PED-D1 2018-DD33

Technical file of the company mentioned below has been inspected and audit has been completed successfully
Pressure Equipment Directive 2014/68/EU – Annex III have been taken as reference for these processes

Manufacturer: **BIOBASE BIODUSTRY (SHANDONG) CO., LTD**
No. 2717 Gongyeyi Road, Mingshui Economic Developing Zone, Zhangqiu, Jinan, Shandong, China

Examination Intent: Examination the completeness of the Technical Documentation according to the requirements of 2014/68/EU Annex III Module D1

Product(s): **Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Autoclave, Portable Autoclave**

Type(s)/Model(s): **BKM-Series, BKQ-Series, BKS-Series** (See details in the attachment)

Type of examination: Quality Assurance of the Production Process

Date of first issue: June 29, 2020

Review Result: This certificate is based on the audit report no. PTPRD01_DD33 issued on 25/06/2018. The result of periodic audits of the quality system is an integral part of this notification. This Certificate of Declaration of full quality assurance is valid until 25/06/2021 and can be withdrawn if surveillance audits show that the quality system no longer complies with the provisions in Annex III module D1.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 the user that identifies the manufacturer as the declarant responsible for supervising the production.

Year of DOC marking: 2020

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

General Manager: *Robert Wang*

Document No: **BKSD-20062901**



Version: BKSD2020 PED DOC 1.0



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ATTACHMENT

Table Top Autoclave Class N Series	BKM-Z12N,BKM-Z18N,BKM-Z24N
Table Top Autoclave Class B Series	BKM-Z16B,BKM-Z18B,BKM-Z24B,BKM-Z45B,BKM-Z60B,BKM-Z80B,BKM-Z18B(III),BKM-Z24B(III),BKM-Z45B(III),BKM-Z60B(III),BKM-Z80B(III)
Table Top Autoclave Class S Series	BKM-Z24S,BKM-Z45S,BKM-Z80S
Table Top Dental Sterilizer	BKM-Z2N,BKM-Z2B,BKM-Z8B,BKM-Z12B
Portable Autoclave	BKM-P18(D),BKM-P24(D),BKM-P18(A),BKM-P24(A),BKM-P18(B),BKM-P24(B)
Cassette Sterilizer	BKS-2000,BKS-5000,BKS-6000
Vertical Autoclave	BKQ-B50I,BKQ-B75I,BKQ-B50II,BKQ-B75II,BKQ-B100II,BKQ-B120II,BKQ-B150II,BKQ-B200II,BKQ-Z30I,BKQ-Z50I,BKQ-Z75I,BKQ-Z100I
Vertical Pulse Vacuum Autoclave	BKQ-B50V,BKQ-B75V
Horizontal Autoclave	BKQ-B100(H),BKQ-B150(H),BKQ-B200(H),BKQ-B300(H)
Horizontal Pulse Vacuum Autoclave	BKQ-Z100(H),BKQ-Z150(H),BKQ-Z200(H),BKQ-Z300(H),BKQ-Z150H,BKQ-Z200H,BKQ-Z260H,BKQ-Z300H
Large Horizontal Autoclave	BKQ-140D-A,BKQ-140DD-A,BKQ-140S-A,BKQ-140SD-A,BKQ-240D-A,BKQ-240DD-A,BKQ-240S-A,BKQ-240SD-A,BKQ-350D-A,BKQ-350DD-A,BKQ-350S-A,BKQ-350SD-A,BKQ-350D-B,BKQ-350DD-B,BKQ-350S-B,BKQ-350SD-B,BKQ-650D-B,BKQ-650DD-B,BKQ-650S-B,BKQ-650SD-B,BKQ-810D-B,BKQ-810DD-B,BKQ-810S-B,BKQ-810SD-B,BKQ-990D-B,BKQ-990DD-B,BKQ-990S-B,BKQ-990SD-B,BKQ-1200D-B,BKQ-1200S-B,BKQ-1500D-B,BKQ-1500S-B
Horizontal Cylindrical Pressure Autoclave	BKQ-H150,BKQ-H200,BKQ-H300,BKQ-H400,BKQ-H500
Gas Sterilizer	BKQ-PS40X,BKQ-PS100X,BKQ-PS100XP,BKQ-PS200X,BKQ-PS200XP

Year of DOC marking: 2020

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

General Manager: Robert Wong

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