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

Company Name:	Biobase Disinfection (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 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016**
Product(s):	**Autoclave**
Type(s)/Model(s):	BKM-Z24B(III), BKM-Z45B(III), BKQ-Z100H
Classification:	**I (according to the classification rules of the MDR)**
Examination Period:	July 8, 2021
Date of Expiry:	July 7, 2026
Review Result:	We, Biobase Disinfection (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 Disinfection (Shandong) Co., Ltd**

RA Specialist: ZHAO

Document No: MDR-Z21070807

CE

Biobase Disinfection (Shandong) Co., Ltd 370124751029O

Digitally signed by Grabazei Alexandru
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