

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 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): Hot Air Sterilizer

Type(s)/Model(s): HAS-T25, HAS-T50, HAS-T70, HAS-T105, HAS-T200

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: 

Document No: MDR-Z21070808

