

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: *A. Wang*

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