

BIOBASE

Biobase Biodustry (Shandong) Co., Ltd.

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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

Harmonised Standards: **EN 13060: 2014; EN 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016**

Product(s): Ekastu SafetyTM CARINAKLEIN DESIGNTM SafetyGlasses

Type(s)/Model(s): **10295132**

Classification: **I (according to the classification rules of the MDD)**

Examination Period: March 19, 2020

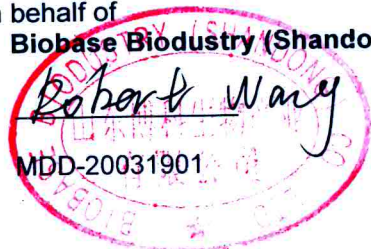
Date of Expiry: March 18, 2025

Review Result: We, Biobase Biodustry (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 93/42/EEC has been detected.

Year of DOC marking: 2020

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

General Manager:

Robert Wang


Document No: MDD-20031901

