

# BIOBASE

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## DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

In Vitro Diagnostic Medical Devices Directive 98/79/EC has been taken as reference for these processes

Company Name: **BIOBASE BIODUSTRY (SHANDONG) CO., LTD.**  
No. 51 South Gongye Road, Jinan, Shandong Province, China

Relevant Directive: **In Vitro Diagnostic Medical Devices Directive-IVDD 98/79/EC**

Product(s): **Elisa Microplate Washer**

Type(s)/Model(s): **BIOBAE-MW9621; BIOBAE-MW9622**

Harmonised standard(s): **EN 61010-2-101:2002; EN 61326-2-6:2006; EN ISO 15223-1:2016; EN ISO 13485:2016; EN ISO 14971:2012; EN ISO 18113-1:2011; EN ISO 18113-3:2011; EN 62366:2008**

Classification: **others (according to In Vitro Diagnostic Medical Devices Directive)**

Examination Period: **July 15, 2019**

Date of Expiry: **July 14, 2024**

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 the Annex II & III of IVDD 98/79/EC has been detected.**

Year of DOC marking: **2019**

Signed for and on behalf of

Company: **BIOBASE BIODUSTRY (SHANDONG) CO., LTD.**

General Manager: **Robert Wang**

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