

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

Company Name:

Biobase Biodustry(Shandong) Co., Ltd.

No.9 Gangxing Road, High-Tech Zone, Jinan City, Shandong Province, China

SRN:

CN-MF-000025015

Related Directives and Annex:

Examination the completeness of the Technical Documentation according to the requirements of 2017/745 (EU)

Related Standards:

EN 60601-1:2006; EN ISO 13485: 2016; EN ISO 15223-1: 2016

Product(s):

Microplate Washer

Type(s)/Model(s):

BK-9613, BK-9621, BK-9622

Basic UDI:

6936895BS0072E

Classification:

I (according to the classification rules of the MDR)

Examination Period:

April 29, 2023

Date of Expiry:

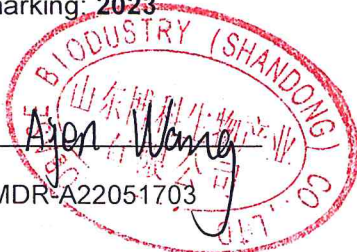
April 28, 2028

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 2017/745/EU has been detected.

Year of DOC marking: 2023

RA Specialist:



Document No: MDR-A22051703

