

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

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): **Table Top Low Speed Centrifuge**

Type(s)/Model(s): **BKC-TL4, BKC-TL4II, BKC-TL4IV, BKC-TL4V, BKC-TL5, BKC-TL5II, BKC-TL5V, BKC-TL5VI, BKC-TL5VII, BKC-TL6, BKC-TL6II, BKC-TL6III, BKC-TL6IV**

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 13532:2002; EN 13612:2002**

Classification: **others (according to classification rules in 98/79/EC)**

GMDN Code: **36465(Centrifuge, general-purpose laboratory)**

Examination Period: **April 28, 2019**

Date of Expiry: **April 27, 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**

Document No: **BKIVD-1904289**

