Declaration of Conformity

Manufacturer:	Biobase Biodustry(Shandong) Co.,Ltd. NO.9 Gangxing Road, High-Tech Zone, Jinan City, Shandong Province, China
SRN:	CN-MF-000025015
whose single Authorized **EU**-*Representative:*	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany SRN:DE-AR-000005110 Lin Sun Tel: 0049- 1715605732 E-mail: info.m@luxuslw.de
Product Name:	5-Part Auto Hematology Analyzer BK-5100, BK-6310, BK-6400, BK-6500, etc.

Basic UDI-DI：6936895BS009-5AHA6S

Classification (IVDR, Annex VIII): Class A, Rule 5, and not for self-testing, not for performance study.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Applied standards, common specification, guidance:
ISO 14971:2019, EN ISO 18113-1:2011, EN 13612:2002/AC:2002,EN 1041:2008+A1:2013, EN ISO 15223-1:2016,IEC 61010-1:2010+AMD1:2016 CSV, IEC 61326-1:2012, IEC 61326-2-6：2012.

Signature: Xumeng Zhang
Date: 2022.09.14
Title: GM
Position: Jinan

Digitally signed by Jighili Tatiana
Date: 2023.08.11 11:48:16 EEST
Reason: MoldSign Signature
Location: Moldova