

## Declaration of Conformity

**Manufacturer:** Biobase Biodustry(Shandong) Co.,Ltd.  
NO 9 Gangxing Road , High-Tech Zone ,Jinan City ,  
Shandong Province, China

**SRN:**  
*whose single* Luxus Lebenswelt GmbH  
*Authorized EU-* Kochstr.1, 47877, Willich, Germany  
*Representative: :* SRN DE-AR-000005110  
Lin Sun  
Tel: 0049- 1715605732  
E-mail: info.m@luxuslw.de

**Product Name:** Automatic Chemistry Analyzer  
BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280,  
BK-200, BK-200mini.etc.

Classification (IVDR, Annex VIII): Class A, Rule 5.

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: 

Date: 2021.9.2

Title: GM

Position: Jinan