

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer: Bioantibody Biotechnology Co., Ltd.
Room 903 & 905, Building C6, No.9, Weidi Road,
Qixia District, Nanjing, China

SRN: CN-MF-000038448

European Representative: MedUnion S.L.
Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain

SRN: ES-AR-000019366

Product Name: Handheld Urine Analyzer

Product Model: BK150

EMDN Code: W02010701

Basic UDI-DI: 697569567902TF

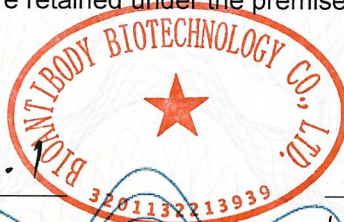
Classification: Class A, Rule 5 (b) of IVDR Annex VIII

Conformity Assessment Procedure: Article 48 (10), IVDR (EU) 2017/746



We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Nanjing 2023.11.1
Place, date



Rui Bing GM.
Legally binding signature, Function