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

CE

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.

BIOANTIBODY BIOTECHNOLOGY CO., LTD. 3201132213939

Nanjing 2023.11.1

Place, date

Rui Bing GM.

Legally binding signature, Function