EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of **NOT Annex II and NOT self-test***)*

Manufacturer:	Safecare Biotech （Hangzhou）Co., Ltd.
Address:	Building 2/203, No.18 Haishu Rd.Cangqian Sub-district， Yuhang District, Hangzhou, Zhejiang China 311121
EC Representative:	Wellkang Ltd Enterprise Hub,NW Business Complex, 1 Beraghmore Road,Derry,BT48 8SE Northern Ireland,UK.

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Multi-drug Rapid Test Kit（Urine） AMP/THC/COC/PCP/OPI/MET/MTD/BAR/BZO/ TCA/MDMA/BUP/EDDP/PPX/ETG/K2/TML/MQ L/COT/FYL/OXY/KET
	Type/model, identification of product allowing traceability (Where applicable)	Device:MDD-1222-A Cup:MDC-1225-A Panel:MDP-1224-A
of Category	: **Common/Others IVD** (Devices of **NOT Annex II** and **NOT self-test**)	

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO23640:2015 EN 13612:2002 EN 13641:2002 EN ISO 14971:2019	EN ISO 18113-1:2011 EN ISO 18113-2:2011 ISO13485:2016 EN ISO15223-1:2016
Conformity assessment procedure	**Module A (EC Declaration of Conformity) (Annex III, except point 6)**	
Notified Body (name & number)	**NOT applicable**	
Certificate & number		

Signed on: 2020.12.31 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp: