# EC Declaration of Conformity

according to the Directive 98/79/EC

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

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|---|---|
| **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<br>Enterprise Hub,NW Business Complex,<br>1 Beraghmore Road,Derry,BT48 8SE Northern Ireland,UK. |

**We, the manufacturer, declare under our sole responsibility that**

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| **the medical device(s)** | Product Name | Multi-drug Rapid Test Kit（Urine）<br>AMP/THC/COC/PCP/OPI/MET/MTD/BAR/BZO/<br>TCA/MDMA/BUP/EDDP/PPX/ETG/K2/TML/MQ<br>L/COT/FYL/OXY/KET |
| | Type/model, identification of product allowing traceability (Where applicable) | Device:MDD-1222-A Cup:MDC-1225-A<br>Panel:MDP-1224-A |
| **of Category** | : **Common/Others IVD**<br>(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.**

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| Applied harmonised standards, national standards or other normative documents | EN ISO23640:2015<br>EN 13612:2002<br>EN 13641:2002<br>EN ISO 14971:2019 | EN ISO 18113-1:2011<br>EN ISO 18113-2:2011<br>ISO13485:2016<br>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:

Digitally signed by Harea Stefan
Date: 2023.04.13 11:02:07 BST
Reason: MoldSign Signature
Location: Moldova