



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
Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn

EC Representative: UnicareQ GmbH
Josephstrasse 6,22041 Hamburg, Germany

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Multi drug Rapid Urine Test
	Type	Panel/Cassette/Cup
	Identifier	AMP/THC/COC/PCP/OPI/MOR/MET/MTD/BAR/BZO/TCA/MDMA/BU P/EDDP/PPX/ETG/K2/TML/MQL/COT/FYL/OXY/KET/KRALSD/CBD/ ETO/PGB/GHB/6-MAM/COD/MDPV/MPD/ZAL/ZOP/GAB/ACE/MCAT/ SOMA/MDA/ZOL/Alfa-PVP/MEP/TPM/ALC/OXI/SG/PH/NIT/GLU/CRE
of Category	Common/Others IVD (Devices of NOT Annex II and NOT self-test) under 98/78/EC , Class B under IVDR 2017/746 Annex VIII	

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 ISO 18113-1:2024
	EN 13612:2002	EN ISO 18113-2:2024
	EN 13641:2002	EN1041- 2016
	EN ISO 14971:2019	ISO 15223-1:2021+Amd 1:2025
	ISO13485:2016	

Conformity assessment procedure **Module A (EC Declaration of Conformity) (Annex III, except point 6)**

Notified Body (name & number) **NOT applicable**

Rev. V4.0

Signed on: 2026.01.16

Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer)



Kebin Qiu Feb. 1.16

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp: