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/BUP/EDDP/PPX/ETG/K2/TML/MQL/COT/FYL/OXY/KET/KRA/LSD/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 13612:2002 EN 13641:2002 EN ISO 14971:2019 ISO13485:2016	EN ISO 18113-1:2024 EN ISO 18113-2:2024 EN1041- 2016 ISO 15223-1:2021+Amd 1:2025
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) _____

Digitally signed by Cobzari-Turcan Rodica
Date: 2026.04.24 10:13:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp: