CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Document No.: TF035-DOC

Manufacturer:	Hangzhou Aichek Medical Technology Co., Ltd
Address:	Jinxing Cun,Yuhang Community,Yuhang District(Future Sci-Tech City),Hangzhou,Zhejiang, P.R.China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	AMP/COC/OPI/K2/BZO/BUP/TCA/PCP/BAR/MOP/MET/KET/MDMA/THC One Step Test
Specification:	Device
Classification：	Others (IVDD)
Conformity Assessment Procedure:	Annex III, except Point 6, of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019	EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN 13612:2002+AC:2002	EN ISO 23640:2015	EN 13641:2002
EN ISO 13485:2016	EN 62366-1:2015	EN ISO 15223-1:2016
EN 13975:2003	EN ISO 17511:2003	

Digitally signed by Jighili Tatiana
Date: 2023.04.14 11:15:11 EEST
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Signature: 张飞锋

Position: Enterprise representative

Date: Dec 10, 2021

Place: Hangzhou/China

杭州艾策医疗技术有限公司
HANGZHOU AICHEK MEDICAL TECHNOLOGY CO., LTD.