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Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Hangzhou Singclean Medical Products Co., Ltd.
No. 125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 310018

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

#	Commercial Name	Generic Device Term	Short description and intended use	GMDN / EDMS Code	Class
1.	Multi-drug One Step Test Kit(Colloidal Gold Method)	Multi-drug One Step Test Kit	The Multi-Drug One Step Test Kit (Colloidal Gold Method) is a rapid chromatographic immunoassay for the qualitative detection for the drugs and drug metabolites in human urine. Testing any combination of the following drugs: Amphetamine(AMP 300), Amphetamine(AMP 500), Amphetamine(AMP), Barbiturates (BAR), Benzoduazepines(BZO100), Benzoduazepines(BZO200), Benzoduazepines(BZO), Buprenorphine(BUP5), Buprenorphine(BUP), Cocaine(COC150), Cocaine(COC), Cotinine(COT), Cotinine(COT 300), Cotinine(COT 600), Methadone metabolite (EDDP), Fentanyl (FYL), Synthetic Cannabis (K2 50), Synthetic Cannabis (K2), Ketamine(KET), Ketamine(KET 500), Methadone(MTD), Methamphetamine(MET300), Methamphetamine(MET500), Methamphetamine(MET), Methylenedioxymethamphetamine(MDMA), Methylenedioxymethamphetamine(MDMA 1000), Morphine(MOP 100), Morphine(MOP 200), Morphine(MOP), Methaqualone (MQL), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Marijuana(THC 25), Marijuana(THC), Tricyclic Antidepressants (TCA), Tramadol (TML), Tramadol (TML300).	12.70.09.70	Others

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards: EN ISO 13485:2016

Corporate Contact Information

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Stamp

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