

Declaration of Conformity

Manufacturer:

Hangzhou Funworld Biotech. Co., Ltd

Room 301, Buliding 1#, 136 Zhiyi Rd, Yuhang Sub-district,
Yuhang District, Hangzhou, Zhejiang, China

whose single Authorized

EU-Representative:

CMC Medical Devices & Drugs S.L

C/Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name:

HCG One Step Pregnancy Test (Urine)
HCG One Step Pregnancy Test (Serum/Urine)
iGFBP-1 Rapid Test (Swab)
fFN Rapid Test (Swab)
cTnI Rapid Test (Whole Blood/Serum/Plasma)
D-dimer Test (Whole Blood/Serum/Plasma)
CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma)
CRP C-Reactive Protein Semi-Quantitative Rapid Test Strip (Whole Blood/Serum/Plasma)
Procalcitonin Rapid Test (Whole Blood/Serum/Plasma)
H. Pylori Ab Rapid Test (Serum/Plasma)
H. Pylori Ag Rapid Test Device (Feces)
Malaria pf whole blood device (Whole Blood)
Malaria pf/pv whole blood device (Whole Blood)
Malaria pf/pan whole blood device (Whole Blood)
Rotavirus Rapid Test Device (Feces)
Adenovirus Rapid Test Device (Feces)
Rota/Adeno combo Rapid Test Device (Feces)
Strep A Rapid Test (Throat Swab)
Dengue IgG/IgM Test Device (Whole Blood/Serum/Plasma)
Dengue Ns1 Test Device (Whole Blood/Serum/Plasma)
Dengue IgG/IgM+Ns1 Combo Test Device (Whole Blood/Serum/Plasma)
Typhoid IgG/IgM Test Device (Whole Blood/Plasma/Serum)
Typhoid Ag Rapid Test Device (Feces)
TB Rapid Test Device (Whole Blood/Plasma/Serum)
Influenza A+B Test (Nasopharyngeal swabs/

Nasal swab)
AMP One Step Amphetamine Test (Urine)
BAR One Step Barbiturates Test (Urine)
BZO One Step Benzodiazepines Test (Urine)
BUP One Step Buprenorphine Test (Urine)
COC One Step Cocaine Test (Urine)
COT One Step Cotinine Test (Urine)
MDMA One Step Ecstasy Test (Urine)
EDDP One Step Test (Urine)
FYL One Step Fentanyl Test (Urine)
KET One Step Ketamine Test (Urine)
THC One Step Marijuana Test (Urine)
MTD One Step Methadone Test (Urine)
MET One Step Methamphetamine Test (Urine)
MQL One Step Methaqualone Test (Urine)
MOP One Step Morphine Test (Urine)
OPI One Step Opiates Test (Urine)
OXY One Step Oxycodone Test (Urine)
PCP One Step Phencyclidine Test (Urine)
PPX One Step Propoxyphene Test (Urine)
TCA One Step Tricyclic Antidepressants Test (Urine)
TML One Step Tramadol Test (Urine)
FOB Rapid Test (Feces)
Microalbumin Rapid Test (Urine)
Ferritin Rapid Test (whole blood/serum/plasma)

Classification: Others of ANNEX II of IVDD

Conformity Assessment Route: Annex III (excluding 6)

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

98/79/EC,EN ISO 13485: 2016,EN 13612:2002,EN 13641: 2002,EN 13975: 2003,EN ISO 14971:2012,EN ISO 15223-1: 2016,EN ISO18113-1:2011,EN ISO18113-2:2011,EN ISO 23640:2015

Signature:**Name:****Title:****Position:**