

## *EC Declaration of Conformity*

**Manufacturer:**

Name: HANGZHOU ALLTEST BIOTECH CO.,LTD.

Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

**European Representative:**

Name: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product (Group) Name: Multi-Drug X (2-12) Drugs Rapid Test Cup

Analyte: Multiple drugs and drug metabolites in human oral fluid

Cat. No.: See Attachment 1

Model: See Attachment 1

Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)

EDMA Code: 12 70 09 70 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. 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.

### DIRECTIVES

**General applicable directives:**

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of First Issue of DOC: in Hangzhou on 04/01/2016

Date of Issue of DOC on 10/05/2022

The Date of DOC Corrigendum on 09/09/2024

Signature: 

Name: GAO FEI (Position: General Manager)



Attachment 1

Catalog No.	Product Name	Analyte	Model
DSD-827	Multi-Drug 2 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-837	Multi-Drug 3 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-847	Multi-Drug 4 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-857	Multi-Drug 5 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-867	Multi-Drug 6 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-877	Multi-Drug 7 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-887	Multi-Drug 8 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-897	Multi-Drug 9 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-8107	Multi-Drug 10 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-8117	Multi-Drug 11 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup
DSD-8127	Multi-Drug 12 Drugs Rapid Test Cup	Multiple drugs and drug metabolites in human oral fluid	Cup