

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 Name: See Attachment 1

Analyte: See Attachment 1

Cat. No.: See Attachment 1

Analyzer/Reader: Lateral Flow Reader

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: See Attachment 1

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.

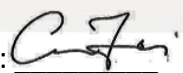
DIRECTIVES

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 Issue: in Hangzhou on 10/05/2022

Signature: 

Name: GAO FEI (Position: General Manager)



Attachment 1

Catalog No.	Product Name	Analyte	EDMA Code	Model
DUA-R127-A1 / DOA-R127-A1	Multi-Drug 2 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R137-A1 / DOA-R137-A1	Multi-Drug 3 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R147-A1 / DOA-R147-A1	Multi-Drug 4 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R157-A1 / DOA-R157-A1	Multi-Drug 5 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R167-A1 / DOA-R167-A1	Multi-Drug 6 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R177-A1 / DOA-R177-A1	Multi-Drug 7 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R187-A1 / DOA-R187-A1	Multi-Drug 8 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R197-A1 / DOA-R197-A1	Multi-Drug 9 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1107-A1 / DOA-R1107-A1	Multi-Drug 10 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1117-A1 / DOA-R1117-A1	Multi-Drug 11 Drugs Rapid Test 1-Step Cup with/without	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup

	Adulteration			
DUA-R1127-A1 / DOA-R1127-A1	Multi-Drug 12 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1137-A1 / DOA-R1137-A1	Multi-Drug 13 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1147-A1 / DOA-R1147-A1	Multi-Drug 14 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1157-A1 / DOA-R1157-A1	Multi-Drug 15 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1167-A1 / DOA-R1167-A1	Multi-Drug 16 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DUA-R1177-A1 / DOA-R1177-A1	Multi-Drug 17 Drugs Rapid Test 1-Step Cup with/without Adulteration	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup
DOA-R1187-A1	<i>Multi-Drug 18 Drugs Rapid Test 1-Step Cup</i>	Multiple drugs and drug metabolites in human urine	12 09 01 90 00	Cup