

EC DECLARATION OF CONFORMITY

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO.,LTD.

Address: #550, Yin Hai 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 (2-20) Drugs Rapid Test Panel with/without Adulteration

Analyte: Multiple drugs and drug metabolites in human urine

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 15/01/2020

Place, Date of Issue: in Hangzhou on 10/05/2022

Signature: 

Name: GAO FEI (Position: General Manager)



Attachment 1

HANGZHOU ALLTEST BIOTECH CO., LTD.

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Catalog No.	Product Name	Analyte	Model
DUA-124 / DOA-124	Multi-Drug 2 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-134 / DOA-134	Multi-Drug 3 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-144 / DOA-144	Multi-Drug 4 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-154 / DOA-154	Multi-Drug 5 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-164 / DOA-164	Multi-Drug 6 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-174 / DOA-174	Multi-Drug 7 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-184 / DOA-184	Multi-Drug 8 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-194 / DOA-194	Multi-Drug 9 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1104 / DOA-1104	Multi-Drug 10 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1114 / DOA-1114	Multi-Drug 11 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1124 / DOA-1124	Multi-Drug 12 Drugs Rapid Test panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1134 / DOA-1134	Multi-Drug 13 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1144 / DOA-1144	Multi-Drug 14 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1154 / DOA-1154	Multi-Drug 15 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1164 / DOA-1164	Multi-Drug 16 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1174 / DOA-1174	Multi-Drug 17 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1184 / DOA-1184	Multi-Drug 18 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel



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DUA-1194 / DOA-1194	Multi-Drug 19 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel
DUA-1204 / DOA-1204	Multi-Drug 20 Drugs Rapid Test Panel with/without Adulteration	Multiple drugs and drug metabolites in human urine	Panel



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