

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: Urinalysis Reagent Strips

Analyte: 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: 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 ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of First Issue of DOC in Hangzhou on 25/05/2022

Signature: _____

Name: Gao Fei (Position: General Manager)



Attachment 1

Catalog NO.	Product Name	Analyte	EDMA Code	Model
U031-01	Urinalysis Reagent Strip	Any one analyte in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-02	Urinalysis Reagent Strips	Any two of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-03	Urinalysis Reagent Strips	Any three of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-04	Urinalysis Reagent Strips	Any four of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-05	Urinalysis Reagent Strips	Any five of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-06	Urinalysis Reagent Strips	Any six of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-07	Urinalysis Reagent Strips	Any seven of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-08	Urinalysis Reagent Strips	Any eight of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip

U031-09	Urinalysis Reagent Strips	Any nine of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-10	Urinalysis Reagent Strips	Any ten of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-11	Urinalysis Reagent Strips	Any eleven of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-12	Urinalysis Reagent Strips	Any twelve of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-13	Urinalysis Reagent Strips	Any thirteen of the following analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip
U031-14	Urinalysis Reagent Strips	All fourteen analytes in human urine: Ascorbic acid, Creatinine, Microalbumin, Glucose, Bilirubin, Ketone Acetoacetic acid, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes, Calcium	11 70 02 02 00	Strip