

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: HCG Pregnancy Enhanced Sensitivity Rapid Test (Urine)

Cat. No.: See Attachment 1

Analyte: Human Chorionic Gonadotropin in human Urine

Model: See Attachment 1

Classification: Self-testing of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex IV

EDMA Code: 12 70 05 02 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 18113-4:2011, EN 13612:2002/AC: 2002, EN ISO 17511:2003,
EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016

Notified body: TUV SUD Product service GmbH, Ridlerstrasse 65, 80339 Munich, Germany
(0123)

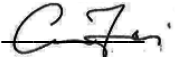
(EC) Certificate(s): V1 095123 0008 Rev.04

Expire date of the Certificate: 2025-05-26

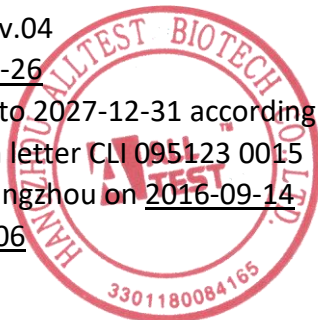
Transitional Period: From 2025-05-26 to 2027-12-31 according to Regulation EU 2024/1860
confirmed with TUV SUD confirmation letter CL 095123 0015

Place, Date of First issue of DOC: in Hangzhou on 2016-09-14

The Date of Issue of DOC on 2025-05-06

Signature: 

Name: GAO FEI (Position: General Manager)



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Attachment 1

Catalog NO.	Product Name	Analyte	EDMA Code	Model
FHC-U101H	hCG Pregnancy Enhanced Sensitivity Rapid Test (Urine)	Human Chorionic Gonadotropin in human Urine	12 70 05 02 00	Dipstick
FHC-U102H	hCG Pregnancy Enhanced Sensitivity Rapid Test (Urine)	Human Chorionic Gonadotropin in human Urine	12 70 05 02 00	Cassette
FHC-U103H	hCG Pregnancy Enhanced Sensitivity Rapid Test (Urine)	Human Chorionic Gonadotropin in human Urine	12 70 05 02 00	Midstream



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