

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 Name: LH Ovulation Rapid Test Dipstick

Analyte: luteinizing hormone (LH) in urine

Model: See attachment 1

Cat. No.: See attachment 1

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

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

EDMA Code: 12 70 05 04 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 (ID: 0123)

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

Expire date of the Certificate: 2025-05-26

First Date of Issue DOC in Hangzhou on 2016-09-14

Date of Issue of DOC: in Hangzhou on 2022-04-05

Signature: 

Name: GAO FEI (Position: General Manager)

Attachment 1

Catalog NO.	Product Name	Analyte	EDMA Code	Model
FLH-101H	<i>LH Ovulation Rapid Test Dipstick</i>	<i>luteinizing hormone (LH) in urine</i>	12 70 05 04 00	Dipstick
FLH-M101H	<i>LH Ovulation Rapid Test Dipstick</i>	<i>luteinizing hormone (LH) in urine</i>	12 70 05 04 00	Dipstick
FLH-U101H	<i>LH Ovulation Rapid Test Dipstick</i>	<i>luteinizing hormone (LH) in urine</i>	12 70 05 04 00	Dipstick
FLH-S101H	<i>LH Ovulation Rapid Test Dipstick</i>	<i>luteinizing hormone (LH) in urine</i>	12 70 05 04 00	Dipstick