



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: PSA Rapid Test Cassette

Analyte: Prostate Specific Antigen (PSA) in human whole blood, serum or plasma

Model: Cassette

Cat. No.: TPS-402

Classification: Annex II, List B of IVDD 98/79/EC

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

EDMA Code: 12 70 03 11 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

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

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

The Date of Issue of DOC on 2022-05-25

Signature:

Name: GAO FEI (Position: General Manager)