

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: HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)

Analyte: Qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human whole blood/Serum /plasma.

Cat. No.: IHBSG-402

Model: Cassette

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

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

EDMA Code: 15 70 02 01 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 corresponding national laws, the provisions of the following EC Council Directives, Standards and Common Technical Specifications. All supporting documentations are retained at the premises of the manufacturer.

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

Common Technical Specifications: COMMISSION DECISION 2002/364/EC (Rev. 2021.03.02)

Notified body: CeCert Sp. z o.o. (ID: 2934)

Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland

(EC) Certificates: CeCert/101/W/E.1 (EC DESIGN-EXAMINATION) & CeCert/102/W/E.1 (FULL QUALITY ASSURANCE SYSTEM)

Expiry Date of the Certificate: 2022.05.16-2025.05.26

Start of CE Marking: 2022.05.16

Place, Date of First Issue of DOC: in Hangzhou on 2022.05.16

Signature: _____

Name: Gao Fei (Position: General Manager)