

## *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: Strep B Rapid Test Cassette

Cat. No.: ISB-502

Analyte: Strep B antigen in human vaginal or rectal swabs

Model: Cassette

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: 15 70 01 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 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 18/12/2019

Date of Issue of DOC on 30/04/2022

Signature: 

Name: GAO FEI (Position: General Manager)