

## *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:** Lyme IgG/IgM Rapid Test Cassette

**Analyte:** IgG & IgM antibodies to Borrelia in human whole blood, serum or plasma

**Cat. No.:** ILY-402

**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 90 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 18/12/2018**

**Date of Issue of DOC on 30/04/2022**

**Signature:** 

**Name:** GAO FEI (Position: General Manager)

