

## *EC Declaration of Conformity*

**Manufacturer:**

**Name:** HANGZHOU BIOTEST BIOTECH CO.,LTD

**Address:** 17#, Futai Road,Zhongtai Street, Yuhang District, Hangzhou -311121  
P.R.China

**European Representative:**

**Name:** Shanghai International Holding Corp. GmbH (Europe)

**Address:** Eiffestrasse 80,20537 Hamburg, Germany

**Product Name:** Clostridium difficile Toxin A+Toxin B Combo Rapid Test Cassette

**Catalog Number:** ICGT-C62

**Classification:** *Non listed Devices of IVDD 98/79/EC*

**Conformity Assessment Route:** *IVDD 98/79/EC Annex III*

*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. Hangzhou Biotest takes exclusive responsibility for this declaration of conformity.*

### **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 ISO14971:2019, EN ISO 18113- 1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 17511:2003, EN ISO 15193: 2009, EN ISO 15194:2009, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 23640:2015, EN 13975:2003, EC 1272/2008**

**Place, Date of Issue:** Hangzhou, P.R. China, May 22, 2022



**Signature:**

**Name :** Wu shujiang

**Position :** General Manager

