

## DECLARATION OF CONFORMITY

**Name and address of manufacturer:** Hangzhou Bioer Technology Co., Ltd.  
1192 BinAn Rd, Binjiang District, 310053 Hangzhou, PEOPLE'S  
REPUBLIC OF CHINA

**SRN of the manufacturer** CN-MF-000019512

**Product Name:** Herpes Simplex Virus Type 1 and 2 Nucleic Acid Typing Detection  
Kit (Fluorescence PCR)

**Cat. Number:** BSJ08S1      BSJ08M1

**Basic UDI-DI:** 697384322BSJ08JQ

**EMDN Code:** W0105040311

Classification according to Annex II of the directive 98/79/EC: General IVDs (Other device not listed under Annex II and self-testing or List A, or List B, or for self-testing).

**Analyte:** Herpes simplex virus type 1 and 2 nucleic acid

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices.

**Conformity Assessment Procedure:** 98/79/EC (IVDD), Annex III

**Notified Body:** Not applicable

**EC certificate number:** Not applicable

**The Authorized EU-Representative** MedNet EC-REP GmbH  
Borkstrasse 10 48163 Muenster, Germany

**SRN of the Authorized Representative:** DE-AR-000000002

**Signature:**

**Print Name & Title:**

**Place & Issuing Date:**

**Valid Until:**

Yu Hai (余海) / General manager

Hangzhou, Zhejiang, China Jan 10, 2022

May 26, 2026 or to the date of issuance of the new DECLARATION OF CONFORMITY, whichever is earlier.

