



## DECLARATION OF CONFORMITY

### Regarding UK Medical Devices Regulations 2002

UKCA-TDS003\_Declaration of Conformity\_A

**Manufacturer:** Hangzhou Bioer Technology Co., Ltd.  
**Address:** 1192 BinAn Rd, Binjiang District, 310053 Hangzhou, PEOPLE'S  
REPUBLIC OF CHINA

**UK Responsible Person:** SUNGO Certification Company Limited  
**Address:** 3rd floor, 70 Gracechurch Street, London. EC3V 0HR

**Product Name:** Monkeypox Virus Nucleic Acid Detection Kit (Fluorescent PCR)  
**Cat. Number:** BSJ32S1      BSJ32M1

**Classification:** General IVDs

**Conformity Assessment Procedure:** Annex III, Part IV of the UK MDR 2002

We herewith declare that the above-mentioned products meet the requirements of UK Medical Devices Regulations 2002 and the following standards.

BS EN ISO 14971:2019      BS EN ISO 15223-1:2016      BS EN ISO 18113-1:2011

**Signature / Date:**   
**Name / Title:** Yu Hai 余海 / General manager  
**Place:** Hangzhou, China



*The declaration of conformity is valid in connection with the release technical document UKCA-TDS003.*