

## DECLARATION OF CONFORMITY

**Manufacturer:** Hangzhou Bioer Technology Co., Ltd.  
**Address:** 1192 BinAn Rd, Binjiang District, 310053 Hangzhou, PEOPLE'S  
REPUBLIC OF CHINA  
**SRN of the manufacturer:** CN-MF-000019512  
**Product Name:** **QuantGene 9600 Fluorescent Quantitative Detection System**  
**Models:** FQD-96C(EA4), FQD-96C(EA5), FQD-96C(EA6),  
**Basic UDI-DI:** 697384322FQD005GY  
**EMDN Code:** W02050116

Classification according to Annex VIII of the Regulation (EU) 2017/746: A, according to rule 5.

**Analyte:** Pathogen Nucleic Acid from Human Specimen

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, which apply to it.

**Conformity assessment procedure:** Conformity declaration according to Annex II & III of the Regulation (EU) 2017/746

**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:** Yu Hai (余海) / General Manager

**Place, Date of Issued:** Hangzhou, April 7, 2022

**Valid Until:** January 1, 2027 or to the date of issuance of the new  
DECLARATION OF CONFORMITY, whichever is earlier.