博日科技
Bioer Technology

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

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:	**LineGene Mini Fluorescent Quantitative Detection System**
Models:	**FQD-16A(EA2R), FQD-16A(EA2H), FQD-16A(EA4)**
Basic UDI-DI:	697384322FQD001GQ
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*

Giám Đốc
CÔNG TY CỔ PHẦN CÔNG NGHỆ TBR
Nguyễn Văn Hưng

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.