

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 MiniS Fluorescent Quantitative Detection System
Models: FQD-16B(EA2), FQD-16B(EA4)
Basic UDI-DI: 697384322FQD002GS
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.