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:	**Automated Nucleic Acid Purification and Real Time PCR System**
Models:	**FQD-A1600(EA4), FQD-A1600(EA5), FQD-A1600(EA6)**
Basic UDI-DI:	697384322FQD006H2
EMDN Code:	W02050116

Classification according to Annex VIII of the Regulation (EU) 2017/746: Class 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.

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
M.S.D.N: 0312549927-C.T.C.P
CÔNG TY CỔ PHẦN CÔNG NGHỆ TBR
Q. BÌNH TÂN - TP. HỒ CHÍ MINH
Nguyễn Văn Hưng

Signature:

Print Name & Title: Yu Hai (余海) / General Manager

Place, Date of Issued: Hangzhou, May 16, 2023

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