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

Name and address of manufacturer:	**Hangzhou Bioer Technology Co., Ltd.** 1192 BinAn Rd, Binjiang District, 310053 Hangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN of the manufacturer	CN-MF-000019512
Product Name:	Neisseria gonorrhoeae, Ureaplasma urealyticum Nucleic Acid Detection Kit (Fluorescent PCR)
Cat. Number:	BSJ22S1
Basic UDI-DI:	697384322BSJ22JJ
EMDN Code:	W0105070501

Classification according to Annex II of the directive 98/79/EC: General IVDs (Other device not listed under Annex II and self-testing or List A, or List B, or for self-testing).

Analyte: Neisseria gonorrhoeae and Ureaplasma urealyticum nucleic acid

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices.

Conformity Assessment Procedure: 98/79/EC (IVDD), Annex III

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 & Issuing Date:	Hangzhou, Zhejiang, China Jan 10, 2022
Valid Until:	May 26, 2027 or to the date of issuance of the new DECLARATION OF CONFORMITY, whichever is earlier.