

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: Group B Streptococcus Nucleic Acid Detection Kit (Fluorescent PCR)

Cat. Number: BSJ07M1

Basic UDI-DI: 697384322BSJ07JN

EMDN Code: W0105011102

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: Human specimen group B streptococcus bacteria 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 Feb 16, 2022

Valid Until: May 26, 2026 or to the date of issuance of the new DECLARATION OF CONFORMITY, whichever is earlier.