CE

DECLARATION OF CONFORMITY

DoC No.: BTTF-010 1.0

Manufacturer:	**Hangzhou Bioer Technology Co., Ltd.** Address: 1192 Bin An Rd, Hi-tech (Binjiang)District, Hangzhou, 310053, P. R. China
Whose Single Authorized EU-Representative:	CMC MEDICAL DEVICES & DRUGS SL C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain Tel: +34951214054 Fax: +34952330100
Product Name:	SARS-CoV-2 /Influenza A Virus / Influenza B Virus Nucleic Acid Detection Kit (Fluorescence RT-PCR)
Cat. Number:	BSJ17S1 BSJ17M1

Classification: Others of ANNEX II of IVDD

Conformity Assessment Route: Annex III

Applicable Standards:

EN ISO 13485:2016	EN ISO 15223-1:2016
EN ISO 14971:2019	EN 13641: 2002
EN ISO 18113-1:2011	EN 13612: 2002
EN ISO 18113-2:2011	EN ISO 23640:2015

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Signature:

Name:

Title: General manager

Position: Hangzhou, China

Date: 2020-12-08