Zhejiang Orient Gene Biotech Co.,Ltd.
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EU DECLARATION OF CONFORMITY ◆ EU-KONFORMITÄTSERKLÄRUNG ◆ DICHIARAZIONE DI CONFORMITÀ UE ◆ DECLARACIÓN UE DE CONFORMIDAD ◆ ДЕКЛАРАЦИЯ СООТВЕТСТВИЯ ЕС ◆ EU 적합성 선언

DECLARAÇÃO DE CONFORMIDADE DA UE ◆ 歐盟符合性聲明 ◆ 欧盟符合性声明

EU Declaration of Conformity

In accordance with Regulation (EU) 2017/746 on In Vitro Diagnostic Regulation

Manufacturer:	Zhejiang Orient Gene Biotech Co., Ltd. 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China.
SRN	CN-MF-000017965
whose single Authorized EU-Representative:	CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
SRN	ES-AR-000000293
Product Name:	COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)
Reference No:	GCFC-T502a-DR
Intended Purpose:	The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are both symptomatic within the first seven days and asymptomatic, influenza A and influenza B in nasal swab specimens directly from individuals who are symptomatic within the first seven days. It is intended to aid in the rapid diagnosis of SARS-CoV-2, influenza A and/or influenza B infections. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) must be confirmed with alternative testing method(s) and clinical findings. It is intended for laboratory professional use. It is not for self testing and not for near patient use.
Basic UDI-DI:	69509960GCFC-T502a-DRHJ
Classification:	Class D Rule 1 of ANNEX VIII of IVDR EU 2017/746
Conformity Assessment Route:	Annex IX

Compliance of the designated product with the Regulation (EU) 2017/746 and Regulation (EU) 2022/1107 has been assessed and certified by the Notified Body

Notified Body ID:	0123
Notified Body:	TÜV SÜD Product Service GmbH
Notified Body Address:	Ridlerstraße 65 80339 München Germany
EU Technical Documentation Assessment Certificate No.:	V70 092305 0009 Rev. 00 Valid until: 2029-12-15
EU quality management system certificate No.:	V10 092305 0004 Rev. 01 Valid until: 2029-02-27

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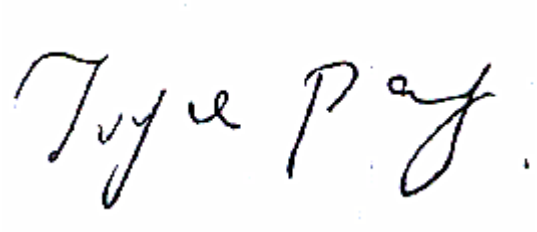
DÉCLARATION UE DE CONFORMITÉ ◆ DECLARACIÓN UE DE CONFORMIDAD ◆ DICHIARAZIONE DI CONFORMITÀ UE ◆ EU-KONFORMITÄTSERKLÄRUNG ◆ EU DECLARATION OF CONFORMITY

EU 적합성 선언 ◆ ДЕКЛАРАЦИЯ СООТВЕТСТВИЯ ЕС ◆ 欧盟符合性声明 ◆ 歐盟符合性聲明 ◆ DECLARAÇÃO DE CONFORMIDADE DA UE

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Device (IVDR) and the Commission Implementing Regulation (EU) 2022/1107. All supporting documentations are retained under the premises of the manufacturer.

Signature:



Name: Joyce Pang
Title: V.P Quality
Position: Anji,Zhejiang, China
Date: 2024-12-20