



CERTIFICATE OF CONFORMITY

Certificate No. : ZUOCE200309610

Company Name : Shanghai Liangrun Biomedicine Technology Co.,Ltd.

Company Address : Level 4 , Building 1, No.271 Gang'ao Road, Pilot Free Trade Zone, Shanghai, China

Product Name : Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19

Related Directives and Annex : 98/79/EC In Vitro Diagnostic Medical Directive

Related Standards : EN ISO 13485:2016; EN ISO 14971:2012; EN 1041:2008; EN ISO 18113-2:2011; EN 13612: 2002; ISO 15223-1:2012; EN ISO 14155:2011; ISO 13640:2002; ISO 23640:2011 EN 980:2008

Examination Intent : *Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Directive 98/79/EC Annex III*

Review result : *During the examination of the provided Technical Documentation (No.:LR-TCF-001, Revision: A/0, dated 2020-MAR-06), no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Directive 98/79/EC Annex III was detected.*

Valid From : 03.09.2020

Valid Until : 03.08.2025



Authorized Signer :



Wallace Xu

Job Title : Certification Manager

The CE Mark may only be used if all relevant and effective EC Directives are complied with