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CE Technical Documentation Review Report

Applicant:	**Core Technology Co., Ltd.** Room 100, C Building, No. 29 Life Park Road, Changping District, 102206 Beijing, China
Report Number:	**50348936 001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	**COVID-19 IgM/IgG Ab Test**
Type(s)/Model(s):	Strip, Cassette
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.05.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CORE-CE-COVID IgM/IgG, Revision V1.1, Dated 2020-Mar-04) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.
Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

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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

CE

Authorized Signer :

Wallace Xu

Job Title : Certification Manager

ZUOCE CERTIFICATION & TESTING CENTER CHINA BRANCH

Date of Issue : 2020-03-09