THE PEOPLE'S REPUBLIC OF CHINA

BUSINESS LICENSE of CORPORATION

Registration No.: 330105000070713

Name of Enterprise: Hangzhou Clongene Biotech Co., Ltd

Legal Representative: Shujian Zheng

Address: 4 Building, 20# Longquan Road, Cangqian Sub-district, Yuhang District, Hangzhou City

Registration Capital: 5,100,000RMB

Paid-up Capital: 5,100,000RMB

Enterprise Type: Limited liability company

Business Scope: Production and sales of non-medical use of biological raw materials(antigens and antibodies); Production of Class 2 and 3, 6840 in vitro diagnostic reagents(Producer License of of Medical Device which is valid until February 10, 2014); sales of subsidiary agricultural products(Excluding the products requiring pre-authorization as per the laws and regulations) and instruments and consultation, and technical service of biological products; Import and export of commodities(excluding business prohibited by the laws and regulations; by license if required); any other legal businesses not requiring authorization.*** By license if required.

Date of Establishment: June 9, 2004

Term of Validity: From June 9, 2004 to June 8, 2014

Note: Please apply for annual verification between March and June each year and visit www.hzaic.gov.cn for instruction.

Registered at Yuhang Branch, Hangzhou Municipal Administration for Industrial and Commerce

Date: December, 2011

医疗器械生产许可证

许可证编号：浙食药监械生产许 20130164 号

企业名称：杭州隆基生物技术有限公司

生产地址：杭州市余杭区余杭街道义创路 1 号

法定代表人：郑曙剑

生产范围：第二、三类 6840 体外诊断试剂***

企业负责人：郑曙剑

住　　所：杭州市余杭区余杭街道义创路 1 号

发证部门：浙江省食品药品监督管理局

有效期限：至　2020　年5　月31　日　　发证日期：　2017　年 2　月22　日

国家食品药品监督管理总局制

杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.
Tel: +86-571-88262120
Fax: +86-571-88261752
Web: www.clongene.com
Email: marketing@clongene.com

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Hangzhou Clongene Biotech Co., Ltd.**
No.1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
China

We declare under our sole responsibility that

the medical device: **COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)-ICOV4212**

of class: **Other**
according to article 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 98/79/EC Annex III**

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Hangzhou, 03/03/2020
Place, date

Shujian Zheng, Legal representative
Name and function

EC Declaration of Conformity
Revision 5.0

中经认证

No：04419E11187R0M

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the environmental system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 913301107620252127

REG./AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

GB/T 24001-2016/ISO 14001:2015 standard

The certificate is valid for the following scope:

ENVIRONMENTAL MANAGEMENT ACTIVITIES OF DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS
(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Nov 11th,2019 Expiry Date:Nov 11th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Nov 11th,2019

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

WeChat Query

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C044-M

地址：北京市西城区月坛北小街4号5号楼1429

中经认证

No：04419Q11975R0M

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the quality management system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 913301107620252127

REG.、AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

GB/T 19001-2016/ISO 9001:2015 standard

The certificate is valid for the following scope:

DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS (WITHIN THE SCOPE OF ADMINISTRATIVE LICENSE)
(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Oct 17th,2019 Expiry Date:Oct 17th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Oct 17th,2019

WeChat Query

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C044-M

地址：北京市西城区月坛北小街4号5号楼1429

中经认证

No：04419S21047R0M

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the occupational health and safety management system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 913301107620252127

REG./AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

ISO 45001：2018 standard

The certificate is valid for the following scope:

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT ACTIVITIES OF DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS

(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Oct 17th,2019

Expiry Date:Oct 17th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Oct 17th,2019

WeChat

Query

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

CNAS 中国认可 管理体系 MANAGEMENT SYSTEM CNAS C044-M

地址：北京市西城区月坛北小街4号5号楼1429

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hangzhou Clongene Biotech Co., Ltd.
No. 1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
China

has established and applies a quality management system for medical devices for the following scope:

Design/development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test of Fertility, Drug of Abuse and Infectious Diseases, In-vitro Diagnostic Rapid Test of Tumour Markers

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-02-06
Certificate Registration No.:	SX 60126181 0001
An audit was performed. Report No.:	15073650 005
This Certificate is valid until:	2020-11-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-02-06

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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