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

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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



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

Hangzhou Clongene Biotech Co., Ltd. Name and address of the manufacturer:

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.

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

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Hangzhou, 03/03/2020 Place, date

Shujian Zheng, Legal representative

Name and function





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中经认证

No: 04419E11187R0M

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

CertificateThis 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

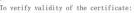
The certificate is valid for the following scope:

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.)

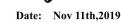
Issue Date:Nov 11th,2019

Expiry Date: Nov 11th, 2022





- verify validity of the certificate: Please scan two-dimensional code on the left
- Access the website www.zjqc.com
- The Certificate is valid ONLY if the







中国认可 MANAGEMENT SYSTEM CNAS C044-M

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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







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



Date: Oct 17th,2019





中国认可 MANAGEMENT SYSTEM CNAS C044-M

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中经认证

No: 04419S21047R0M

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM **CERTIFICATION**

 $\begin{tabular}{ll} \pmb{Certificate} \\ \hline \textbf{This is to certify the occupational health and safety management system of} \\ \hline \end{tabular}$

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.)

Expiry Date:Oct 17th,2022

ongjing Quality Certification Co., Ltd. General Manager:







He Qct 17th 201

To verify validity of the certificate:

Please scan two-dimensional code on the left
 Access the website www.zjqc.com
 Access the website of CNCA www.cnca.gov.cn

The Certificate is valid ONLY if the organization pass the surveillance audit Date: Oct 17th,2019



MANAGEMENT SYSTEM CNAS C044-M

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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

Date 2018-02-06

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

020 d 04.08
TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approve