

Certificate CN21/42239

The management system of

# Guangzhou Decheng Biotechnology Co., Ltd.

Room 218 and Room 212, Building 2, No. 68, Nanxiang 1<sup>st</sup> Road,  
Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016



For the following activities

**Design, Manufacture and Distribution of Human Chorionic Gonadotropin (HCG) Digital Pregnancy Rapid Test and In Vitro Diagnostic Test Kits for Detection of 2019-nCoV.**

This certificate is valid from 16 March 2021 until 15 March 2024  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 14 March 2024  
Issue 1. Certified since 16 March 2021

Authorised by

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

HC SGS 13485 2016 0118

Page 1 of 1



0005





此为证书 CN21/42239 译本  
This is an SGS translation of CN21/42239 Issue 1

下述组织

# 广州德成生物科技有限公司

中国广东省广州市黄埔区科学城南翔一路 68 号  
2 栋 218 房、2 栋 212 房



的管理体系已经过审核,并被证明符合下述要求

## ISO 13485:2016 EN ISO 13485:2016

所涉及的活动范围覆盖

人绒毛膜促性腺激素(HCG)电子检测笔以及用于新型冠状病毒肺炎  
检测的体外诊断试剂盒的设计、制造和销售

该证书的有效期自 2021-03-16 至 2024-03-15  
并须经过符合要求的监督审核保持有效  
持续认证需在 2024-03-14 之前执行  
版本号 1. 初始注册日期 2021-03-16

签署



0005

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

第1页 共1页



本文件由本公司根据公布在其网站  
[www.sgs.com/terms\\_and\\_conditions.htm](https://www.sgs.com/terms_and_conditions.htm) 中的认证服务通用条款颁发。提  
请注意其中已确定的责任范围、赔偿和可管辖事项。本文件的真  
实性可在网站 <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory> 中核实。任何未经授权的对此文件的内容或外观的变更、  
伪造或篡改皆属非法,违反者将会被依法追诉。