

此为证书 CN21/42278 译本
This is an SGS translation of CN21/42278 Issue 1

下述组织

北京金沃夫生物工程科技 有限公司

注册地址：中国北京市丰台区科学城星火路 10 号 1 号楼 420 室



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

所涉及的活动范围显示在第二页

该证书的有效期自 2021-04-9 至 2024-04-8
并须经过符合要求的监督审核保持有效
持续认证需在 2024-03-18 之前执行
版本号 1. 初始注册日期 2021-04-9

该证书为多地址证书, 其它具体地址在后续页上列出

签署



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此为证书 CN21/42278 译本，续
This is an SGS translation of CN21/42278 Issue1, Continued

北京金沃夫生物工程科技 有限公司

ISO 13485:2016 EN ISO 13485:2016



Issue 1

所涉及的活动范围覆盖

基于免疫层析法的体外诊断试剂的设计开发、生产和分销包括
优生优育检测试剂盒、妇科阴道炎症检测试剂盒、小儿腹泄病
毒检测试剂盒、呼吸系统疾病检测试剂盒、肺炎检测试剂盒、
胃肠疾病检测试剂盒、性传染疾病检测试剂盒、新型冠状病毒
(2019-nCoV) 抗原检测试剂盒，新型冠状病毒 (2019-nCoV)
IgG/IgM 抗体检测试剂盒

附属机构

经营地址：中国北京市大兴区金苑路 26 号 1 幢 206 室



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Certificate CN21/42278

The management system of

Beijing Jinwofu Bioengineering Technology Co., Ltd.

Business Registration Address: Room 420, 1st Building, No. 10, Xinghuo Road, Science City, Fengtai District, Beijing, 100070, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 April 2021 until 8 April 2024 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 18 March 2024 Issue 1. Certified since 9 April 2021

This is a multi-site certification. Additional site details are listed on the subsequent page.

Authorised by

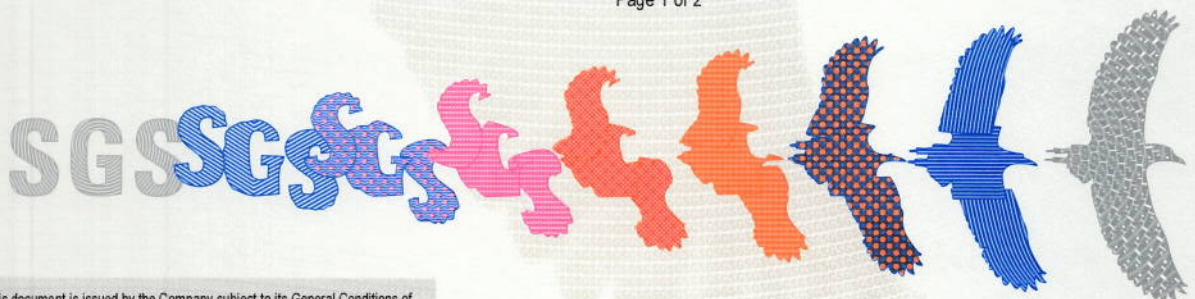


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Beijing Jinwofu Bioengineering Technology Co., Ltd.

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Issue 1

Detailed scope

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Reagents based on Immunochromatography, including Eugenics Test Kit, Gynecologic Vaginal Inflammation Test Kit, Diarrhea Virus in Children Test Kit, Respiratory Diseases Test Kit, Pneumonia Test Kit, Gastrointestinal Disease Test Kit, Sexually Transmitted Diseases Test Kit, Novel Coronavirus (SARS-CoV-2) Antigen Test Kit, Novel Coronavirus(SARS-COV-2) IgM/IgG Antibody Test Kit

Additional facilities

Business Operation Address: Room 206,1st Building, No. 26, Jinyuan Road,
Daxing District, Beijing, 102600, P.R. China



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