



兹证明

## 厦门奥德生物科技有限公司

统一社会信用代码: 913502050899181912

经营地址: 厦门市海沧区新园路 120 号 503 单元、1203 单元

注册地址: 厦门市海沧区新园路 120 号 503 单元

的质量管理体系适用于

体外诊断试剂的生产及销售(资质许可范围内, 明细见附件); 新型冠状病毒 IgM/IgG 抗体测定试剂盒(胶体金法); 新型冠状病毒抗原快速检测试剂盒(胶体金法)的生产和销售(出口欧盟)

已经 NQA 根据标准

**ISO 13485:2016**

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系, 并由 NQA 进行监督。

获证组织必须定期接受监督审核并经审核合格, 此证书方继续有效。

本证书信息可在国家认证认可监督管理委员会官方网站([www.cnca.gov.cn](http://www.cnca.gov.cn))上查询

SNQA 查询网站: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**46652**

Date:

09 July 2019

Reissue Date:

16 April 2021

Valid Until:

09 July 2022





This is to certify that the Quality Management System of

## Xiamen AmonMed Biotechnology Co., Ltd.

**Unified Social Credit Code:** 913502050899181912

**Operation Address:** Unit 503 & 1203, 120 Xinyuan Road, Haicang District, Xiamen City, Fujian Province, China

**Registered Address:** Unit 503, 120 Xinyuan Road, Haicang District, Xiamen City, Fujian Province, China

applicable to

Production and sales of in vitro diagnostic reagents (within the scope of qualification, see attachment for details); production and sales of COVID-19 IgM/IgG test kit(Colloidal Gold); COVID-19 antigen rapid test kit(Colloidal Gold)(export to EU)

has been assessed and registered by NQA against the provisions of

### ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website: [www.snqa.com.cn](http://www.snqa.com.cn)

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## 厦门奥德生物科技有限公司

### 附件

1. D-二聚体 (D-Dimer) 测定试剂盒 (荧光免疫层析法)
2. 降钙素原 (PCT) 测定试剂盒 (荧光免疫层析法)
3. 微量白蛋白 (U-ALB) 测定试剂盒 (荧光免疫层析法)
4. 全称C-反应蛋白 (hsCRP+常规CRP) 测定试剂盒 (荧光免疫层析法)
5. 细菌唾液酸酶测定试剂盒 (唾液酸酶法)
6. 隐血 (Hb/Tf) 双联测定试剂盒 (胶体金法)
7. 肌钙蛋白I (cTnI) 测定试剂盒 (荧光免疫层析法)
8. 肌酸激酶同工酶 (CKMB) 测定试剂盒 (荧光免疫层析法)
9. 肌红蛋白 (Myo) 测定试剂盒 (荧光免疫层析法)
10. 胱抑素C (CysC) 测定试剂盒 (荧光免疫层析法)
11. N末端脑利钠肽前体 (NT-proBNP) 测定试剂盒 (荧光免疫层析法)
12. 糖化血红蛋白 (HbA1c) 测定试剂盒 (荧光免疫层析法)
13. 心脏型脂肪酸结合蛋白 (H-FABP) 测定试剂盒 (荧光免疫层析法)
14.  $\beta$  2 微球蛋白 ( $\beta$  2-MG) 测定试剂盒 (荧光免疫层析法)
15. 中性粒细胞明胶酶相关脂质运载蛋白 (NGAL) 测定试剂盒 (荧光免疫层析法)
16. 25-羟基维生素 D (25-OHVD) 测定试剂盒 (荧光免疫层析法)
17. 肌钙蛋白 I/肌酸激酶同工酶/肌红蛋白 (cTnI/CKMB/Myo) 测定试剂盒 (荧光免疫层析法)
18. 新型冠状病毒(2019-nCoV)IgM/IgG 抗体检测试剂盒 (稀土纳米荧光免疫层析法)

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## Xiamen AmonMed Biotechnology Co., Ltd.

### Annex

1. Kit for the Determination of D-Dimer (Fluorescence Immunochromatography)
2. Kit for the Determination of Procalcitonin (Fluorescence Immunochromatography)
3. Kit for the Determination of Urine Microalbumin(U-ALB) (Fluorescence Immunochromatography)
4. Kit for the Determination of The whole course of C-Reactive Protein (hsCRP+CRP) (Fluorescence Immunochromatography)
5. Bacterial Vaginosis Test Kit (Sialidase)
6. Occult Blood (Hemoglobin/Transferrin) Test Kit (Colloidal Gold)
7. Kit for the Determination of Troponin I (Fluorescence Immunochromatography)
8. Kit for the Determination of Creatine Kinase-MB (Fluorescence Immunochromatography)
9. Kit for the Determination of Myoglobin (Fluorescence Immunochromatography)
10. Kit for the Determination of Cystatin C (Fluorescence Immunochromatography)
11. Kit for the Determination of N-terminal pro-brain natriuretic (Fluorescence Immunochromatography)
12. Kit for the Determination of Hemoglobin A1c (Fluorescence Immunochromatography)
13. Kit for the Determination of Heart-type Fatty Acid Binding Protein(Fluorescence Immunochromatography)
14. Kit for the Determination of  $\beta$ 2 Microglobulin (Fluorescence Immunochromatography)
15. Kit for the Determination of Neutrophil gelatinase-associated (Fluorescence Immunochromatography)
16. Kit for the Determination of 25-OH Vitamin D(Fluorescence Immunochromatography)
17. Kit for the Determination of Troponin I /CKMB/Myoglobin(Fluorescence Immunochromatography)
18. COVID-19 IgM/IgG Test Kit (Rare Earth Nano Fluorescence Immunochromatography)

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