



# MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. 117 21 QOM 0153 R0S

This is to certify that **Tianjin Galenus Medical Co., Ltd.**

Unified social credit code 91120222MA7M1XN95C

Location **Room 403, 4th Floor, Building C02,  
Pioneering Headquarters Base,  
Wuqing District, Tianjin, P.R.China**

has been assessed and registered as meeting the requirements of

**ISO13485:2016**

Scope of approval **Production and Export of Colloidal Gold Reagents for Detecting Multiple Biomarkers In Vitro (Assay Reagents for the Prediction and Auxiliary Diagnosis of Infectious Disease, Cardiovascular and Cerebrovascular Disease, Narcotics Ingredients and Hormone Indexes)**

First Certification: 30 Jul. 2021

Expiry Date: 29 Jul. 2024

Signed by:



Shanghai Ingeer Certification Assessment Co., Ltd.

Certification and Accreditation Administration of PRC: CNCA-R-2003-117

Tel: 400-182-9001/+86 21-51114700

Web: www.icas.org.cn

Add: Room 801, HuaDing Mansion, 2368# West Zhongshan Rd.,

Xuhui District, Shanghai, China, 200235



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First Surveillance Audit	Second Surveillance Audit	Third Surveillance Audit
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The ownership of the certificate belongs to Shanghai Ingeer Certification Assessment Co., Ltd. The information & validation of this certificate can be checked on the CNCA website: WWW.CNCA.GOV.CN and ICAS website, or by calling ICAS's clients services Dept. The certificate is only valid when used together with related permits when appropriate. If the organization can't effectively maintain the above management system, ICAS has the right to withdraw the qualification certificate.



# 医疗器械质量管理体系 认证证书

认证编号：117 21 QOM 0153 ROS

兹证明 **天津盖伦医学科技有限公司**

统一社会信用代码：91120222MA7M1XN95C

地址：天津市武清开发区福源道北侧创业总部基地C02号楼403室

经现场评审满足：ISO 13485:2016 医疗器械质量管理体系用于法规的要求

认证范围：**体外检测多种生物标志物的胶体金试剂（用于传染性疾**  
**病、心脑血管疾病、毒品成分及激素指标的预测和辅助诊断的测定检**  
**测试剂）的生产及外销**

核 准：



初次发证：2021年07月30日

有效期至：2024年07月29日

上海英格尔认证有限公司

国家认监委批准号：CNCA-R-2003-117

电话：400-182-9001/+86 21-51114700

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