

# 质量管理体系认证证书

证书编号: 00121Q312356R0M/3600  
兹证明

江西科美医疗器械集团有限公司

统一社会信用代码: 913601246834681112

中国江西省南昌市进贤县长山乡新居 (316 国道旁)

建立的质量管理体系符合标准:

GB/T 19001-2016 / ISO 9001:2015

通过认证范围如下:

资质范围内医疗器械的生产 (一次性使用医用外科口罩、一次性使用外科口罩帽子、一次性使用医用粘贴敷料、一次性使用医用粘贴薄膜手术巾、医用一次性防护服、红外额温计、一次性使用医用橡胶检查手套、医用纱布敷料、医用输液贴、一次性使用手术帽子、一次性使用灭菌橡胶外科手套、一次性使用医用手术衣、一次性使用医用手术垫单、纱布绷带、棉签、检查手套、造口袋、透气胶带、隔离衣、医用隔离鞋套、医用隔离面罩、医用隔离眼罩、一次性使用病毒采样管、鼻氧管)

首次发证日期: 2021年12月27日 本次发证日期: 2021年12月27日 有效期至: 2024年12月26日

在一个监督周期后, 本证书必须与CQC签发的监督审核合格通知书合使用方可有效。查询证书有效状态请登陆[www.cqc.com.cn](http://www.cqc.com.cn)。  
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



中国认可  
国际互认  
管理体系  
MANAGEMENT SYSTEM  
CNAS C001-M

谢肇煦

Signed by: Xie ZhaoXu

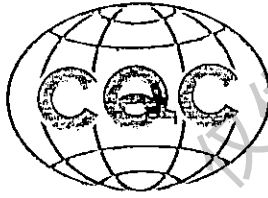


## 中国质量认证中心

中国·北京·南四环西路188号9区 100070  
<http://www.cqc.com.cn>

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# QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121Q312356R0M/3600

We hereby certify that

**Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.**

Unified Social Credit Code: 913601246834681112

No. 316, National Road, Xinju, Changshan Town, Jinxian County, Nanchang City, Jiangxi Province, P.R. China

by reason of its

**Quality Management System**

has been awarded this certificate for compliance with the standard

**GB/T 19001-2016 / ISO 9001:2015**

The Quality Management System Applies in the following area:

Manufacturing of medical consumables within the scope of the certification (Disposable Medical Surgical Masks, Disposable Surgical Masks and Caps, Disposable Medical Gauze Dressings, Disposable Medical Surgical Drapes, Disposable Medical Protective clothing, Infrared Forehead Thermometers, Sterile Latex Examination Gloves for Single Use, Disposable Medical Wound Dressings, Disposable Medical Infusion Plasters, Disposable Surgical Caps, Sterile Latex Surgical Gloves for Single Use, Disposable Surgical Gowns, Disposable Medical Adhesive Films, Disposable Medical Gauze Bandages, Disposable Medical Cotton Swabs, Examination Gloves, Disposable Medical Colostomy Bags, Disposable Medical Breathable Adhesive Tapes, Disposable Medical Isolation Gowns, Disposable Medical Shoe Covers, Disposable Medical Face Shields, Disposable Medical Goggles, Disposable Sampling Tubes, Disposable Nasal Oxygen Tubes)

Certified since: December 27, 2021 Valid from: December 27, 2021 Valid until: December 26, 2024

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC. Please access [www.cqc.com.cn](http://www.cqc.com.cn) for checking validity of the certificate.

This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)).



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国际互认  
管理体系  
MANAGEMENT SYSTEM  
CNAS C001-M

谢肇煦

Signed by: Xie ZhaoXu

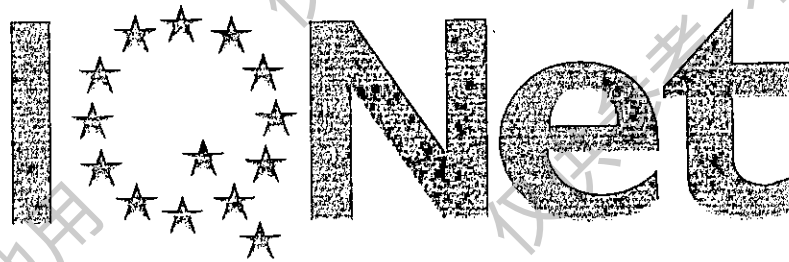


**CHINA QUALITY CERTIFICATION CENTRE**

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China  
<http://www.cqc.com.cn>

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THE INTERNATIONAL CERTIFICATION NETWORK  
**CERTIFICATE**

*CQC has issued an IQNet recognized certificate that the organization:*  
**Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.**

No. 316, National Road, Xinju, Changshan Town, Jinxian County, Nanchang City, Jiangxi Province, P.R. China

*has implemented and maintains a*  
**Quality Management System**

*for the following scope:*

Manufacturing of medical consumables within the scope of the certification (Disposable Medical Surgical Masks, Disposable Surgical Masks and Caps, Disposable Medical Gauze Dressings, Disposable Medical Surgical Drapes, Disposable Medical Protective clothings, Infrared Forehead Thermometers, Sterile Latex Examination Gloves for Single Use, Disposable Medical Wound Dressings, Disposable Medical Infusion Plasters, Disposable Surgical Caps, Sterile Latex Surgical Gloves for Single Use, Disposable Surgical Gowns, Disposable Medical Adhesive Films, Disposable Medical Gauze Bandages, Disposable Medical Cotton Swabs, Examination Gloves, Disposable Medical Colostomy Bags, Disposable Medical Breathable Adhesive Tapes, Disposable Medical Isolation Gowns, Disposable Medical Shoe Covers, Disposable Medical Face Shields, Disposable Medical Goggles, Disposable Sampling Tubes, Disposable Nasal Oxygen Tubes)

*which fulfils the requirements of the following standard:*

**GB/T 19001-2016 / ISO 9001:2015**

*Issued on:* December 27, 2021

*Expires on:* December 26, 2024

**Registration Number: CN00121Q312356R0M/3600**

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*



Alex Stoichitoiu  
President of IQNet

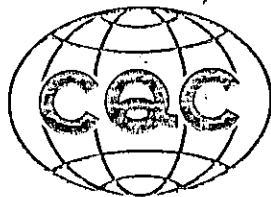
Xie ZhaoXu  
President of CQC



**IQNet Partners\*:**

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
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NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
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# 环境管理体系认证证书

证书编号: 00121E35310R1M/3600

兹证明

江西科美医疗器械集团有限公司

中国江西省南昌市进贤县长山乡新居 (316国道旁)

建立的环境管理体系符合标准:

GB/T 24001-2016 / ISO 14001:2015

通过认证范围如下:

资质范围内医疗器械的生产及相关管理活动 (一次性使用医用外科口罩、一次性使用外科口罩帽子、一次性使用医用粘贴敷料、一次性使用医用粘贴薄膜手术巾、医用一次性防护服、红外额温计、一次性使用医用橡胶检查手套、医用纱布敷料、医用输液贴、一次性使用手术帽子、一次性使用灭菌橡胶外科手套、一次性使用医用手术衣、一次性使用医用手术垫单、纱布绷带、棉签、检查手套、造口袋、透气胶带、隔离衣、医用隔离鞋套、医用隔离面罩、医用隔离眼罩、一次性使用病毒采样管、鼻氧管)

首次发证日期: 2019年1月11日 本次发证日期: 2021年12月30日 有效期至: 2025年1月10日

在一个监督周期后, 本证书必须与CQC签发的监督审核合格通知书合并使用方可有效。查询证书有效状态请登陆 [www.cqc.com.cn](http://www.cqc.com.cn)。  
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



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谢肇煦  
Signed by: Xie ZhaoXu

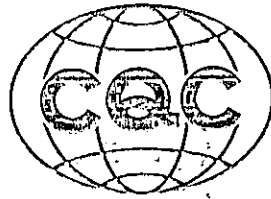


## 中国质量认证中心

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<http://www.cqc.com.cn>

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# ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121E35310R1M/3600

We hereby certify that

**Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.**

No. 316, National Road, Xindu, Changshan Town, Jinxian County, Nanchang City, Jiangxi Province, P.R. China

by reason of its

## Environmental Management System

has been awarded this certificate for compliance with the standard

**GB/T 24001-2016 / ISO 14001:2015**

The Environmental Management System Applies in the following area:

Manufacturing of medical consumables within the scope of the certification and Related Management Activities (Disposable Medical Surgical Masks, Disposable Surgical Masks and Caps, Disposable Medical Gauze Dressings, Disposable Medical Surgical Drapes, Disposable Medical Protective clothings, Infrared Forehead Thermometers, Sterile Latex Examination Gloves for Single Use, Disposable Medical Wound Dressings, Disposable Medical Infusion Plasters, Disposable Surgical Caps, Sterile Latex Surgical Gloves for Single Use, Disposable Surgical Gowns, Disposable Medical Adhesive Films, Disposable Medical Gauze Bandages, Disposable Medical Cotton Swabs, Examination Gloves, Disposable Medical Colostomy Bags, Disposable Medical Breathable Adhesive Tapes, Disposable Medical Isolation Gowns, Disposable Medical Shoe Covers, Disposable Medical Face Shields, Disposable Medical Goggles, Disposable Sampling Tubes, Disposable Nasal Oxygen Tubes)

**Certified since: January 11, 2019 Valid from: December 30, 2021 Valid until: January 10, 2025**

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC. Please access [www.cqc.com.cn](http://www.cqc.com.cn) for checking validity of the certificate.

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MANAGEMENT SYSTEM  
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谢肇煦  
Signed by: Xie ZhaoXu



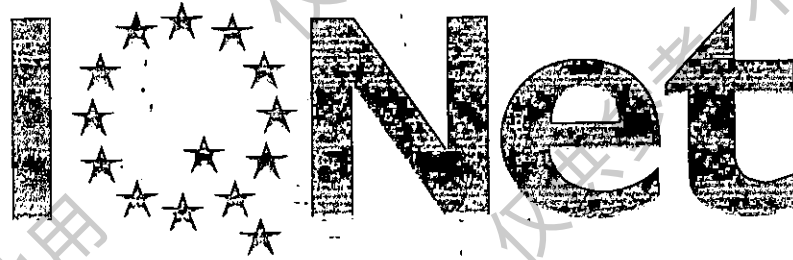
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No. 316, National Road, X inju, Changshan Town, Jinxian County, Nanchang City, Jiangxi Province, P.R. China

*has implemented and maintains an*  
**Environmental Management System**

*for the following scope:*

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*which fulfils the requirements of the following standard:*

GB/T 24001-2016 / ISO 14001:2015

Issued on: December 30, 2021

Expires on: January 10, 2025

Registration Number: **CN00121E35310R1M/3600**

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Alex Stoichitoiu  
President of IQNet

Xie ZhaoXu  
President of CQC



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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
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