



兹证明

长沙仁基医疗器械有限公司

统一社会信用代码: 91430181MA4RPFWQ23

经营地址: 湖南省长沙市浏阳市经济技术开发区湘台路 18 号长沙 E 中心四期 201 号房、301 号房、401 号房

注册地址: 湖南省长沙市浏阳市经济技术开发区湘台路 18 号长沙 E 中心四期 201 号房

的质量管理体系适用于

一次性使用病毒采样管、一次性使用采样器、核酸提取或纯化试剂、一次性使用唾液采集器、一次性使用粪便采集器、一次性使用尿液采集器、运送培养基、医用退热贴、穴位压力刺激贴、导光凝胶、创口贴、一次性使用人体静脉血样采集容器的研发、制造和销售（许可资质范围内）；样本采集容器、培养皿、PCR 管、血清移液管、一次性使用吸管、一次性使用吸头、试管、离心管、冻存管、深孔板、针式过滤器、静脉按压医用敷贴的销售（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）上查询

SNQA 查询网站: www.snqa.com.cn

L.N. Sh
总经理

证书号: 133421

初次发证日期: 2024 年 01 月 17 日

证书有效期至: 2027 年 01 月 17 日



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使用 UKAS 认可标志表明对 NQA 所持有的编号为 015 的认可证书所覆盖的活动进行认可:

NQA 是 NQA 认证有限公司的商业名称, 注册号为 09351758。注册地址: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, 英国:

证书为 NQA 所有, 客户需在 NQA 要求时将证书返还;

上海恩可埃认证有限公司, 地址: 中国 (上海) 自由贸易试验区陆家嘴环路 958 号 2201 室。



This is to certify that the Quality Management System of

Changsha Renji Medical Equipment Co., Ltd.

Unified Social Credit Code: 91430181MA4RPFWQ23

Operation Address: 201, 301, 401, Stage 4, Changsha E Center, No. 18 Xiangtai Road, Liuyang Jingkai District, Changsha City, Hunan Province, China

Registered Address: 201, Stage 4, Changsha E Center, No. 18 Xiangtai Road, Liuyang Jingkai District, Changsha City, Hunan Province, China

applicable to

Design, Manufacture and Sales of Disposable Virus Specimen Collection Tube, Disposable Sampling Swab, Viral RNA&DNA Extraction Kit, Saliva Collection Kit, Disposable Stool Container, Disposable Urine Container, Transport Medium, Cooling Patch, Acupoint Pressure Patch, Conductive Gel, Wound Plaster, Blood Collection Tube(within the scope of Permitted Qualifications);

Sales of Sample Containers, Petri Dish, PCR Tube, Serological Pipette, Transfer Pipette, Pipette Tip, Test Tube, Centrifuge Tube, Cryovials, Deepwell Plate, Needle Filters and Disposable Automatic Venous Compression Band(Export to the EU)

has been assessed and registered by NQA against the provisions of

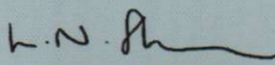
ISO 13485:2016

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)

SNQA's website: www.snqa.com.cn


Managing Director

Certificate Number: **133421**

Issue Date: 17 January 2024

Valid Until: 17 January 2027



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The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.