

# 医疗器械质量管理体系认证证书

证书编号：933231020017ROM

兹证明

## 湖南臻和亦康医疗用品有限公司

统一社会信用代码：914303007632785298

注册地址：湖南省湘潭市高新区双马街道霞光东路 55 号湖南京湘节能科技园生产装备车间 6 栋

经营地址：湖南省湘潭市高新区双马街道霞光东路 55 号湖南京湘节能科技园生产装备车间 6 栋，8 栋 3、4、5 楼

经现场评审符合

### YY/T 0287-2017 /ISO13485:2016 《医疗器械质量管理体系用于法规的要求》标准

认证范围

资质许可范围内病人护理防护用品，手术室感染控制用品，医护人员防护用品，包扎敷料，不可吸收外科敷料，呼吸、麻醉用管路，非血管内导管，口腔治疗器具，医用棉签的生产

发证日期：2023-08-29

有效期至：2026-08-28

证书签发人：

沈卉



本证书信息可在中国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)) 查询，亦可登录亿寰认证中心有限公司官方网站 ([www.yihuaniso.com](http://www.yihuaniso.com)) 查询或扫描二维码查询

亿寰认证中心有限公司

有效期三年内需两次现场监督审核，首次监督审核在初审后12个月内，此后监督审核至少每个日历年进行一次

湖南省长沙市芙蓉区定王台街道解放中路136号蓝色地标1205

# MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.933231020017R0M

This is to certify that:

## Hunan Zhenhe Yikang Medical Products Co., Ltd.

Unified social credit code: 914303007632785298

Registered Address: Building 6, Production Equipment Workshop, Hunan Jingxiang Energy Conservation Technology Park, No. 55, Xiaguang East Road, Shuangma Street, High tech Zone, Xiangtan City, Hunan Province

Auditing Address: 3rd, 4th, and 5th floors of Building 8, Building 6, Production Equipment Workshop, Hunan Jingxiang Energy Conservation Technology Park, No. 55, Xiaguang East Road, Shuangma Street, High tech Zone, Xiangtan City, Hunan Province

has been assessed and certified in compliance with the standard

### YY/T 0287-2017 /ISO13485:2016

Scope of Approval: Production of patient care protective equipment, operating room infection control equipment, medical staff protective equipment, bandaging dressings, non absorbable surgical dressings, respiratory and anesthesia pipelines, non vascular catheters, oral treatment equipment, and medical cotton swabs within the scope of qualification permit

Issue Date: 29/08/2023

Expiry Date: 28/08/2026

Issued by: 沈奇



亿寰认证中心



The information of this certificate can be inquired on the official website of China National Certification and Accreditation Administration ([www.cnca.gov.cn](http://www.cnca.gov.cn)), You can also log in to the official website of Yihuan Certification Center Co., Ltd. ([www.yihuaniso.com](http://www.yihuaniso.com)) or scan the QR code to inquire

Yihuan Certification Center Co., Ltd.

Two on-site supervision and audits are required within three years of validity, The first surveillance audit will be conducted within 12 months after the initial audit, and thereafter surveillance audits will be conducted at least once every calendar year



# 医疗器械质量管理体系认证证书附件

证书编号：933231020017ROM

序号	场所名称	地址	过程/活动/产品	备注
1	成品仓库	湖南省湘潭市岳塘区楚天路 19 号	成品储存	

注：本附件与证书同时使用方为有效；本附件的监督审核情况应与证书监督审核情况一致

发证日期：2023 年 08 月 29 日

有效期至：2026 年 08 月 28 日



证书签发人：沈卉