



# 认证证书

N. CN22 - 30974H

兹证明

龙口市三益医疗器械有限责任公司

统一社会信用代码: 913706815522016527

注册地址

山东省龙口市黄城车站北 2 公里路西

办公及生产地址

山东省烟台市龙口市黄城车站北 2 公里路西

完成医疗器械质量管理体系审核并符合以下标准要求

## ISO 13485:2016

认证范围:

医用 X 射线防护服系列 (只限一类) 的生产和销售  
(资质许可范围内)

类别: A. 1. 1

有关此认证证书状态的更多信息, 请通过电话+355696037861/+39 0296368458 联系或发送邮件至 info@axe-register.com 或使用组织名称或证书编号在 www.axe-register.com 网站验证。

该证书须接受定期的年度监督审核和三年一次的完整体系评审确保其有效性。

初次注册日期: 2022 年 12 月 08 日  
发证日期: 2022 年 12 月 08 日  
证书有效期至: 2025 年 12 月 07 日



CS 007 26.02.18

EA/MLA 签署, 多边互认协议



授权人签字  
AXE REGISTER Ltd  
Antonio Llayda

(1)  
监督审核  
合格标签  
粘贴处

(2)  
监督审核  
合格标签  
粘贴处

在证书有效期内每 12 个月内须接受一次监督审核并将监督审核合格标签粘贴于右侧指定位置, 此证书方为有效。本证书可在国家认证认可监督管理委员会网站(www.cnca.gov.cn)查询。

AXE REGISTER

中国总部: 艾西姆认证(上海)有限公司, 中国上海市闵行区外环路 352 号 B201 室, 邮政编码: 201199  
电话: +86 21 64305860 传真: +86 21 64881096 网址: www.acmcert.com.cn 邮箱: info@acmcert.com.cn



# CERTIFICATE

**N. CN22 – 30974H**

This is to certify that the Quality Management System of Medical Devices of

**LONGKOU SANYI MEDICAL DEVICE CO.,LTD.**

**Unified social credit code:** 913706815522016527

**Registered Address**

2KM OF HUANGCHENG STATION NORTH.LONGKOU CITY

**Office & Production Address**

2Km of Huangcheng Station North.Longkou City, Yantai City  
Shandong Province, China

Has been independently assessed and found in conformance with the standard

**ISO 13485:2016**

For the following scope of activities:

**Production and Sales of Medical X-Ray Protective Clothing Series  
(Only Class I) (Within the Scope of Qualification)**

**Category:** A.1.1

For further and updated information regarding any changes in the status of this certification please contact via phone under +355696037861 / +39 0296368458 or via email to [info@axe-register.com](mailto:info@axe-register.com) or verify directly on the website [www.axe-register.com](http://www.axe-register.com) by using the organization name or the certificate number.

The validity of this certificate is subject to periodic yearly surveillance audit and triennial review of the entire management system of the certified organization.

<b>Date of first registration</b>	<b>08/12/2022</b>
<b>Date of this certificate</b>	<b>08/12/2022</b>
<b>Date of expiry</b>	<b>07/12/2025</b>



CS 007 26.02.18

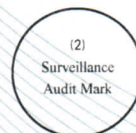
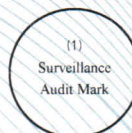


Signatory of EA/MLA, Mutual Recognition Agreements

On behalf of the Certification Body  
**AXE REGISTER Ltd**

*Antonio Lavda*  
Technical Director

During validity period of the certificate a surveillance audit should be carried out once within each 12 months. The label should be pasted on specified position of right side of the certificate then it is valid. The certificate can be checked out at CNCA website ([www.cnca.gov.cn](http://www.cnca.gov.cn)).



**AXE REGISTER**

Piazza Unità d'Italia, 5 - 21047 Saronno (VA) - Italia | +39 02 96368458 | [info@axe-register.com](mailto:info@axe-register.com)  
ACM (CHINA) LIMITED, Rm B201, No 352, Waihuan Road, Minhang District, Shanghai 201199, China