



America

# CERTIFICATE

No. QS6 102732 0001 Rev. 02

**Certificate Holder:** **Jiangsu Huayuan Medical Technology CO., LTD.**  
No.36 Nanzhuang Road  
High-Tech Industrial Development Zone  
224249 Dongtai City, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacture and Distribution of Disposable Medical Examination Glove**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002822**

**Effective Date:** **2022-12-30**

**Expiry Date:** **2025-12-29**

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**Date of Issue:** 2023-01-09

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services



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**Regulatory Requirements:     Audit/Certification Criteria**

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**United States**

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

**Facility(ies):**

Jiangsu Huayuan Medical Technology CO., LTD.  
No.36 Nanzhuang Road, High-Tech Industrial Development  
Zone, 224249 Dongtai City, Jiangsu, PEOPLE'S REPUBLIC OF  
CHINA

**Facility Scopes:**

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of Disposable Medical Examination Glove  
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