

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2097821-1

Organization: Jiangxi Hawk Medical Supplies Co., Ltd.  
Torch Road, High tech park, Fengcheng City,  
Yichun City  
331100 Jiangxi  
P.R. China

Scope: Manufacture and Distribution of Disposable Infusion Enteral Giving Sets,  
Disposable Feeding Bags, Disposable High-Pressure Angiographic  
Syringes, Disposable Infusion Sets for Infusion Equipment Use, Disposable  
Infusion Sets

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244423109-200  
Effective date: 2023-03-06  
Expiry date: 2025-12-28  
Issue date: 2023-03-06



Herbert Zhong  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60148250 0001

**Report No.:** 15096361 002

**Manufacturer:** Jiangxi Hawk Medical Supplies  
Co., Ltd.  
Torch Road, High tech park, Fengcheng City  
Yichun City  
331100 Jiangxi  
P.R. China

**Products:** Disposable Infusion Enteral Giving Sets, Disposable  
High-Pressure Angiographic Syringes, Disposable Infusion  
Sets for Infusion Equipment Use, Disposable Infusion Sets  
Aspects of manufacture concerned with securing and  
maintaining sterile conditions: Disposable Feeding Bags

**Expiry Date:** 2024-04-30

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-03-20

**Date:** 2020-03-20

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.



2024-02-21

## To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer Jiangxi Hawk Medical Supplies Co., Ltd. has lodged an application for conformity assessment based on MDR (EU) 2017/745 Annex IX Chapter I, Section 2 and 3 and Chapter III.

MDD Certificate No: DD 60148250 0001, expiry date: 2024-04-30.  
Jiangxi Hawk Medical Supplies Co., Ltd. signed the MDR certification contract on 2024-02-20, Quotation No. 245830703, The quotation is a formal contract between Jiangxi Hawk Medical Supplies Co., Ltd. and TÜV Rheinland (Shanghai) Co., Ltd.

The transition timelines according to (EU) 2023/607 are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

TÜV Rheinland (Shanghai) Co., Ltd. will continue to do MDD surveillance audit for the manufacturer Jiangxi Hawk Medical Supplies Co., Ltd.

Yours sincerely,  
TÜV RHEINLAND (SHANGHAI) Co., Ltd.



Mr. Tony Chen  
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