

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 DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Jiangxi Hawk Medical Supplies Co.,Ltd.**

**Torch Road, High tech park, Fengcheng City
Yichun City 331100 Jiangxi P.R. China**

We declare under our sole responsibility that

The following medical device:

- a. **Disposable High-Pressure Angiographic Syringes, Class IIa Rule 2**
- b. **Pressure Connecting Tubes, Class IIa Rule 2**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex V**

Registration No.: **DD 60148250 0001**

Notified Body: **CE 0197**

TUV Rheinland LGA Products GmbH

Tillystraße 2-90431 Nurnberg Deutschland

Jiangxi, 2021-11-22

Place, date

Name: Jianxin Zhu, function: General Manager



Attached product list

No.	Product Name/产品名称	Models/型号	Classification/分类
1	Disposable High-Pressure Angiographic Syringes	50ml,60ml,65ml,100 ml,115ml,125ml,130 ml,140ml,150ml,200 ml	Ila Rule 2
2	Pressure Connecting Tubes	CT, MRI, DSA	Ila Rule 2

