

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

Herbert Zhong



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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following 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**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-20
Certificate Registration No.: SX 60148251 0001
An audit was performed. Report No.: 15096361 002
This Certificate is valid until: 2022-04-30

Certification Body



Date 2020-03-20



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety