



I.V. Catheter, pen-like  
Y-A



I.V. Catheter with wings  
Y-BZ



I.V. Catheter with wings  
and injection port Y-B



I.V. Catheter with small wing  
Y-AY



Y-AS Safety I.V. Catheter



Y-BS



IV. Cannula with  
Heparin Injection  
Y-AZ



"Y" Type I.V. Catheter  
Y-BC

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Suzhou Lingyan Medical  
Technology Co., Ltd.**  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

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

**(see attachment for scope)**

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: 2019-01-16  
Certificate Registration No.: SX 60130007 0001  
An audit was performed. Report No.: 16802607 007  
This Certificate is valid until: 2021-12-09

Certification Body



Date 2019-01-16



**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>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60130007 0001  
**Report No.:** 16802607 007

**Organization:** Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Scope:**

Design and Development, Manufacture and Distribution of

- Disposable Infusion Pumps
- Disposable I.V. Catheters
- Disposable Hypodermic Needles
- Disposable Injection Needles for Mixing Medicines
- Disposable Vacuum Blood Collection Tubes
- Disposable Self-destruction Safety Syringes with Needles
- Disposable Oxygen Masks
- Disposable EMG Needles
- Disposable Safety Blood Collection Needles

Provision of Ethylene Oxide Sterilization service for  
Single-use Medical Devices in accordance  
with EN ISO 11135:2014

**Certification Body**



**Date: 2019-01-16**





**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60135413 0001

**Report No.:** 16802607 007

**Manufacturer:** Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Products:** Medical Devices  
  
(see attachment for products included)

Replaces Approval, Registration No.: HD 60107681 0001

**Expiry Date:** 2023-12-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-01-16

**Date:** 2019-01-16

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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60135413 0001  
**Report No.:** 16802607 007

**Manufacturer:** Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Products:**

- Disposable Infusion Pumps
- Disposable I.V. Catheters
- Disposable Hypodermic Needles
- Disposable Oxygen Masks
- Disposable EMG Needles
- Disposable Self-destruction Safety Syringes with Needles
- Disposable Safety Blood Collection Needles

Aspects of manufacture concerned with securing  
and maintaining sterile conditions:

- Disposable Injection Needles for Mixing Medicines

**Date:** 2019-01-16

**Notified Body**



**Herbert Zhong**