



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

**Registration No.:** DD 60138030 0001

**Report No.:** 15068619 008

**Manufacturer:** Shaoxing Yibon Medical Co., Ltd.  
No. 341 Yuewang Road  
Paojiang Industrial Zone  
Shaoxing  
312000 Zhejiang  
China

**Products:** Medical Devices  
  
(see attachment for products and additional site included)  
  
Replaces Approval, Registration No.: DD 60093942 0001

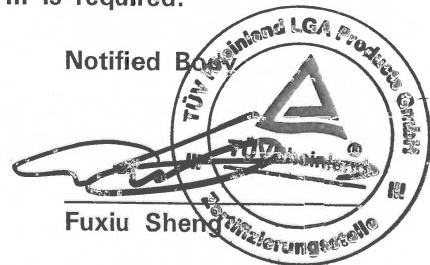
**Expiry Date:** 2024-05-27

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:** 2019-06-18

**Date:** 2019-06-18

Notified Body



Fuxiu Sheng

**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**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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**Report No.:** 15068619 008

**Manufacturer:** Shaoxing Yibon Medical Co., Ltd.  
No. 341 Yuewang Road  
Paojiang Industrial Zone  
Shaoxing  
312000 Zhejiang  
China

**Products:**

Sterile Gauze Abdominal Swabs, Sterile Gauze Swabs/Balls with X-ray Detectable Threads, Sterile Non-woven Abdominal Swabs, Sterile Non-Woven Swabs/Balls with X-ray Detectable Threads, Surgical Dressing Sets, Infusion Dressing Sets;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Catheterization Sets, Sterile Dialysis Sets, Sterile Gauze Swabs/Balls, Sterile Non-Woven Swabs/Balls, Sterile Non-woven Absorbent Pads, Sterile Non-woven Wound Dressings, Sterile Dressing Sets, Sterile Eye Pads, Sterile Bandages, Sterile Forceps, Sterile Film Wound Dressings, Sterile Drapes, Suture Remover Sets, Staple Remover Sets, Medical Bowl Sets, Disinfection Sets, Foam Dressings

**Site included:**

No. 347 Yuewang Road, Paojiang Industrial Zone,  
Shaoxing, Zhejiang 312000, China

**Date:** 2019-06-18

