

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

Registration No.: DD 60093942 0001

Report No.: 15068619 001

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 60025680 0001

Expiry Date: 2019-06-16

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: 2014-06-17

Date: 2014-06-17



Notified Body

X. Ren

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**

Registration No.: DD 60093942 0001
Report No.: 15068619 001

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: 2014-06-17



Notified Body

X. Ren