

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Yinjing Medical Technology
(Shanghai) Co., Ltd.
No. 586, Yuanxi Rd.
Nanhui Industry Park
201300 Shanghai
China**

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

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-06-30

Certificate Registration No.: SX 60111701 0001

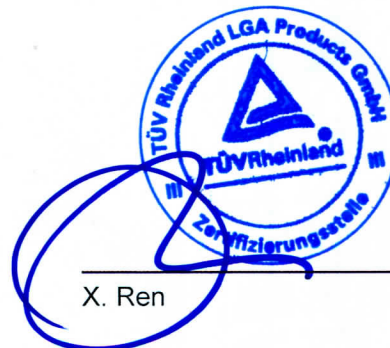
An audit was performed. Report No.: 15089863 003

This Certificate is valid until: 2019-01-06

Certification Body



Date 2016-06-30



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

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60111701 0001
Report No.: 15089863 003

Organization: Yinjing Medical Technology
(Shanghai) Co., Ltd.
No. 586, Yuanxi Rd.
Nanhui Industry Park
201300 Shanghai
China

Scope:

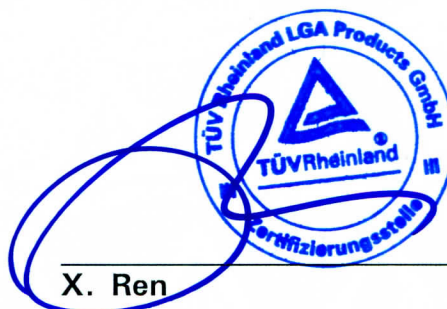
Products:

- Sterile Medical Gauze Series (Gauze Sponges with X-ray Detectable, Gauze Balls with X-ray Detectable, Lap Sponges)
- Medical Devices Disinfectant Wipes
- Alcohol Swabs
- Alcohol Swabsticks
- Sterile Surgical Scrubs
- Surgical Operational Kits
- Sterile Medical Gauze Series (Gauze Sponges, Gauze Balls, Gauze Blocks, Olefin Gauzes, Face Masks)
- Sterile Non-woven Series (Absorbent Pads, Dressings, Non-woven Pads, Non-woven Balls, Non-woven Towels, Non-woven Caps, Non-woven Shoes, Non-woven Masks, Adhesive Aperture Drapes, Wet Wipes)
- Sterile Medical Cotton Series (Medical Cotton Wools, Medical Cotton Balls, Medical Cotton Tips, Sanitary Towels, Surgical Pads)

Certification Body



Date: 2016-06-30



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60111701 0001
Report No.: 15089863 003

Organization: Yinjing Medical Technology
(Shanghai) Co., Ltd.
No. 586, Yuanxi Rd.
Nanhui Industry Park
201300 Shanghai
China

Scope:

Products:

- Surgical Gown Series (Surgical Gowns, Isolation Gowns)
- Bandage Series (Gauze Bandages, Non-woven Bandages, Medical Cotton Bandages, Elastic Bandages)
- First Aid Kits
- Dressing Kits

Certification Body



Date: 2016-06-30



X. Ben

中文翻译件仅供参考

认 证 证 书

认证机构 TÜV Rheinland LGA Products GmbH, 兹证明下述公司:

银京医疗科技(上海)股份有限公司
中国上海市浦东新区南汇区
工业园区园西路 586 号
201300

已在如下领域建立并应用了医疗器械质量管理体系:

生产和销售医疗器械
(产品见附件)

证明该质量管理体系满足了下列标准的要求

EN ISO 13485:2012

EN ISO 13485:2012/AC:2012

此质量管理体系是基于年度监督审核基础上的。

证书生效日:	2016-06-30
证书登记号:	SX 60111701 0001
审核已进行, 报告号:	15089863 003
证书有效期至:	2019-01-06



日期: 2016-06-30

认 证 机 构

Gesehen/Reviewed
Shanghai V. Lin Zhang 2016-7-19
TÜV Rheinland LGA Products GmbH
X. Ren

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

附件

登记号: **SX 60111701 0001**

报告号: **15089863 003**

制造者: **银京医疗科技（上海）股份有限公司**

中国上海市浦东新区南汇区工业园区园西路 586 号
201300

范 围:

产品:

- 无菌医用纱布系列（纱布片，X 线纱布片，纱布球，X 线纱布球，纱布块，腹部垫子，石蜡纱布，口罩）
- 医疗器械消毒湿巾
- 消毒擦片
- 消毒棉棒
- 灭菌医用手术刷
- 外科手术包
- 无菌医用纱布系列（纱布片，纱布球，纱布块，石蜡纱布，口罩）
- 无菌无纺布系列（吸水垫，敷料垫，无纺布片，无纺布球，无纺布巾，无纺布帽，无纺布鞋，无纺布口罩，消毒片，粘性洞巾，湿巾）
- 无菌药棉系列（医用药棉，医用棉球，医用棉签，产妇巾，纱布夹棉片，酒精棒）



日期: **2016-06-30**

 Gesehen/Reviewed
Shanghai. Vivian Zhang 2016-7-19
TÜV Rheinland LGA Products GmbH
X.Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 - 90431 Nürnberg

附件

登记号: **SX 60111701 0001**

报告号: **15089863 003**

制造者: **银京医疗科技（上海）股份有限公司**
中国上海市浦东新区南汇区工业园区园西路 586 号
201300

范 围:

产品:

- 手术衣系列（手术衣，隔离衣）
- 绷带系列（纱布绷带，无纺布绷带，三角绷带，弹性绷带）
- 急救包
- 敷料包



日期: **2016-06-30**



Gesehen/Reviewed
Shanghai.. *Vivian Zhang* 2016-7-19
TÜV Rheinland LGA Products GmbH
X.Ren