

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

Registration No.: DD 60111700 0001

Report No.: 15089863 003

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60109882 0001

Expiry Date: 2021-01-06

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: 2016-06-30

Date: 2016-06-30

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. 1/2, Rev. 0

**Attachment to
Certificate**

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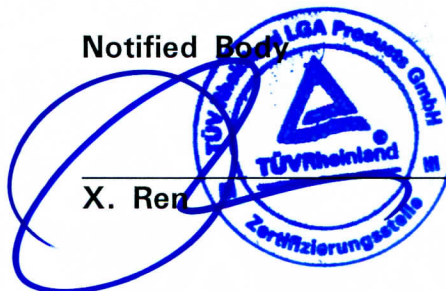
Products:

- 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

Date: 2016-06-30

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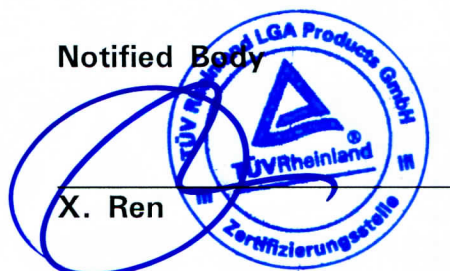
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Aspects of manufacture concerned with securing and
maintaining sterile conditions:

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

Date: 2016-06-30

Notified Body



中文翻译件仅供参考

EC 证 书

指令 93/42/EEC 附录五 生产质量保证体系

登 记 号: DD 60111700 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

产 品: 医疗器械
(产品见附件)
替代批准, 注册号: DD 60109882 0001

有 效 期 至: 2021-01-06

公告机构在此认可指令 93/42/EEC 附录五之第三款的要求, 就所列产品而言得到满足。上述公司建立并实施的质量管理体系, 本批准书将依据指令附录五第四款的规定定期监督。如果本证书涉及到 IIb 和 III 类产品要上市, 还需要设计文档检查证书。

生效日期: 2016-06-30

公 告 机 构

日期: 2016-06-30

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

TÜV Rheinland LGA Products GmbH –Tillystraße 2 - 90431 Nürnberg

根据医疗器械指令 93/42/EEC 的规定

TÜV Rheinland LGA Products GmbH 为公告机构, 公告号是 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 - 90431 Nürnberg

附 件

登 记 号: DD 60111700 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

产 品:

- 无菌医用纱布系列（X线纱布片，X线纱布球，腹部垫）
- 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

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: **DD 60111700 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

以下的医疗器械范围覆盖生产工艺中有关无菌状态的保护和维护:

- 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、黏性洞巾、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）
- 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

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