



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 046241 0064 Rev. 04

Manufacturer

Winner Medical Co., Ltd.

Winner Industrial Park
No. 660 Bulong Road
Longhua District
518109 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Gauze Products,
Synthetic Non-woven Products,
100% Cotton Non-woven Products,
Cotton Products, Special Dressing
Products
(for detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19043CN01

Valid from: 2019-12-09

Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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Facility(ies):

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District,
518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Winner Medical (Jingmen) Co., Ltd.

Special No.1, Hangkong Avenue, Pailou, 448121 Jingmen, Hubei,
PEOPLE'S REPUBLIC OF CHINA

Winner Medical (Jiayu) Co., Ltd.

No. 172, Fenghuang Avenue, 437200 Jiayu, Hubei, PEOPLE'S
REPUBLIC OF CHINA

Winner Medical (Chongyang) Co., Ltd.

Te 1, Winner Avenue, Qingshan Industrial Zone, Qingshan Town,
437542 Chongyang, Hubei, PEOPLE'S REPUBLIC OF CHINA

Winner Medical (Huanggang) Co., Ltd.

Winner Industrial Park, Te 1, Chibi Road, 438000 Huanggang,
Hubei, PEOPLE'S REPUBLIC OF CHINA

Winner Medical (Chongyang) Co., Ltd.

No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang,
Hubei, PEOPLE'S REPUBLIC OF CHINA

Winner Medical (Chongyang) Co., Ltd.

No. 9A, Jincheng Avenue, Zhongjin Village, Tiancheng Town,
437500 Chongyang, Hubei, PEOPLE'S REPUBLIC OF CHINA

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Gauze Products:

Swabs/Sponges (plain and fluff) without X-ray detectable element, Lap Sponges (washed, unwashed and fluff) without X-ray detectable element, Balls without X-ray detectable element, Rolls without X-ray detectable element, O.R. Towels without X-ray detectable element, Trach Sponges without X-ray detectable element

In Facility:

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100% Cotton Non-woven Products

Swabs/Sponges without X-ray detectable element, Lap Sponges without X-ray detectable element, Balls without X-ray detectable element, Rolls without X-ray detectable element, O.R. Towels without X-ray detectable element, Trach Sponges without X-ray detectable element

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Synthetic Non-Woven Products

Swabs/Sponges without X-ray detectable element, Lap Sponges without X-ray detectable element, Balls without X-ray detectable element, Rolls without X-ray detectable element, Face Mask, Caps, Shoe Covers, Surgical Gown, Protective Clothes, Isolation Clothes, Bed Sheets, Pillows, Quilt Covers, Sleeves, Aprons, Beard covers, Drapes

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Winner Medical (Huanggang) Co., Ltd.

Winner Industrial Park, Te 1, Chibi Road, 438000 Huanggang, Hubei, P.R. China

Special Dressing Products

Basic Dressing Packs with Class I element, Sterile First Aids, Sterile Finger Bandage for Medical Use, Sterile Applicator for Medical Use, Alcohol Pad, Cast Padding, Wound Dressing, Silicone Band Aid

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Winner Medical (Chongyang) Co., Ltd.

No. 9A, Jincheng Avenue, Zhongjin Village, Tiancheng Town, 437500 Chongyang, Hubei, P.R. China

Cotton Products

Oval Formed Eye Pads, Cotton Wool (cotton roll), Cotton Ball, Zig-zag Cotton Wool, Dental Sponges,
Combine Dressings

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