



Product Service

# Certificate

**No. Q5 046241 0068 Rev. 04****Holder of Certificate: Winner Medical Co., Ltd.**

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

**Certification Mark:**

**Scope of Certificate:** Design and Development, Production and Distribution of  
Bandages and wound dressings,  
Other medical devices for wound care,  
Non-active dental equipment and instruments,  
Non-active non-implantable devices for anaesthesia,  
emergency and intensive care

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 046241 0068 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5 046241 0068 Rev. 04)

**Report No.:** SH2204301**Valid from:** 2023-07-06**Valid until:** 2026-05-31**Date,** 2023-07-06

Christoph Dicks  
Head of Certification/Notified Body



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D-ZM-11321-01-00



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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **Winner Medical Co., Ltd.**  
Winner Industrial Park, No. 660 Bulong Road, Longhua District,  
518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of below  
products :

Gauze Products, including: Sterile and Non-Sterile  
Swabs/Sponges without/with X-ray Detectable Element, Sterile  
and Non-Sterile Lap Sponges without/with X-ray Detectable  
Element, Sterile and Non-Sterile Balls without/with X-ray  
Detectable Element, Sterile and Non-Sterile Rolls without/with X-  
ray Detectable Element, Sterile and Non-Sterile Trach Sponges,  
Sterile and Non-Sterile O.R. Towels, Sterile and Non-Sterile  
Medical Use Gauze Face Masks

Cotton Non-Woven Products, including: Sterile and Non-Sterile  
Swabs/Sponges without/with X-ray Detectable Element, Sterile  
and Non-Sterile Lap Sponges without/with X-ray Detectable  
Element, Sterile and Non-Sterile Balls without/with X-ray  
Detectable Element, Sterile and Non-Sterile Rolls without/with X-  
ray Detectable Element, Sterile and Non-Sterile O.R. Towels,  
Sterile and Non-Sterile Trach Sponges, Sterile and Non-Sterile  
Cotton Spunlace Non-Woven Surgical Gown

Synthetic Non-Woven Products, including: Sterile and Non-Sterile  
Swabs/Sponges without/with X-ray Detectable Element, Sterile  
and Non-Sterile Lap Sponges without/with X-ray Detectable  
Element, Sterile and Non-Sterile Balls without/with X-ray  
Detectable Element, Sterile and Non-Sterile Rolls without/with X-  
ray Detectable Element, Sterile and Non-Sterile Medical Use Face  
Masks, Sterile and Non-Sterile Medical Use Caps, Sterile and  
Non-Sterile Medical Use Shoe Covers, Sterile and Non-Sterile  
Surgical Gowns, Sterile and Non-Sterile Medical Use Protective  
Clothes, Sterile and Non-Sterile Medical Use Isolation Gown,  
Sterile and Non-Sterile Medical Use Bed Hygienic Sheets, Sterile  
and Non-Sterile Medical Use Hygienic Pillow Covers, Sterile and  
Non-Sterile Medical Use Sleeve Covers, Sterile and Non-Sterile  
Medical Use Aprons, Sterile and Non-Sterile Surgical Drapes,  
Sterile and Non-Sterile Non-Surgical Drapes

Bandages and Tapes, including: Non-Sterile Triangular Bandages,  
Non-Sterile Gauze Bandages, Non-Sterile Elastic Bandages, Non-  
Sterile Elastic Adhesive Bandages, Non-Sterile Plaster of Paris  
Bandages, Non-Sterile Soft Silicone Tapes, Sterile and Non-Sterile  
Silicone Plaster

Special Dressing Products, including: Sterile and Non-Sterile  
Hydrocolloid Plaster, Sterile and Non-Sterile Plaster, Non-Sterile  
Finger Bandage, Sterile and Non-Sterile Medical Use Applicators,

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Non-Sterile Sterilization Pouches, Sterile and Non-Sterile Medical Use Bibs, Sterile and Non-Sterile Tongue Depressors, Sterile and Non-Sterile Medical Tapes, Sterile and Non-Sterile Medical Use Paper Towel, Sterile and Non-Sterile Medical Use PE Sleeve Covers, Sterile and Non-Sterile Medical Use PE Aprons, Sterile and Non-Sterile Medical Use PE Gloves, Sterile and Non-Sterile Medical Use PE Shoe Covers, Sterile and Non-Sterile Medical Use Alcohol Pad, Sterile and Non-Sterile Undercast Padding, Sterile and Non-Sterile Non-woven Wound Dressing, Sterile and Non-Sterile Transparent wound Dressing, Sterile and Non-Sterile Alginate Dressing, Sterile and Non-Sterile Foam Dressing, Sterile and Non-Sterile Hydrocolloid Dressing, Sterile and Non-Sterile Super Absorbent Dressing, Sterile and Non-Sterile Silicone Foam Dressing, Sterile and Non-Sterile Silicone Wound Contact Layer, Sterile and Non-Sterile Activated Charcoal Super Absorbent Dressing, Sterile and Non-Sterile NPWT Gauze Dressing Kit, Sterile and Non-Sterile NPWT Foam Dressing Kit, Sterile and Non-Sterile Silicone Super Absorbent Dressing, Sterile and Non-Sterile CMC Gelling Fiber Dressing, Sterile and Non-Sterile Silicone Scar Repair Sheet, Sterile and Non-Sterile Hydrogel, Sterile and Non-Sterile Hydrogel Impregnated Gauze Dressing, Sterile and Non-Sterile Skin Protective Barrier, Sterile and Non-Sterile Adhesive Remover Pad, Sterile and Non-Sterile Hydrogel Burn Bandage, Sterile and Non-Sterile Silicone Scar Gel, Sterile and Non-Sterile Hydrogel Sheet Dressing, Sterile and Non-Sterile Non Adhesive Dressing

Cotton Products, including: Sterile and Non-Sterile Medical Use Cotton Roll, Sterile and Non-Sterile Medical Use Cotton Ball, Sterile and Non-Sterile Medical Use Cotton Swab, Sterile and Non-Sterile Medical Use Eye pad, Sterile and Non-Sterile Dental Cotton, Sterile and Non-Sterile ABD Pad, Sterile and Non-Sterile Gauze combine Cotton pad, Sterile and Non-Sterile Gauze combine Cotton ball, Sterile and Non-Sterile Nursing Pad

Sterile and Non-Sterile Basic Dressing Packs



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## Facility(ies):

Winner Medical (Jingmen) Co., Ltd.  
Special No.1, Hangkong Avenue, Pailou, 448121 Jingmen, Hubei,  
PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of below products :

Gauze Products, including: Non-Sterile Lap Sponges without X-ray Detectable Element, Non-Sterile Lap Sponges with X-ray Detectable Element, Non-Sterile Medical Use Gauze Face Masks

Cotton Non-Woven Products, including: Non-Sterile Lap Sponges without X-ray Detectable Element, Non-Sterile Lap Sponges with X-ray Detectable Element, Non-Sterile Cotton Spunlace Non-Woven Surgical Gown

Synthetic Non-Woven Products, including: Non-Sterile Lap Sponges without X-ray Detectable Element, Non-Sterile Lap Sponges with X-ray Detectable Element, Non-Sterile Surgical Gowns, Non-Sterile Medical Use Protective Clothes, Non-Sterile Medical Use Isolation Gown

Bandages and Tapes, including: Non-Sterile Triangular Bandages



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## Facility(ies):

Winner Medical (Jiayu) Co., Ltd.  
No. 172, Fenghuang Avenue, 437200 Jiayu, Hubei, PEOPLE'S  
REPUBLIC OF CHINA

Production and Distribution of below products :

Special Dressing Products, including: Sterile and Non-Sterile Medical Use Applicators, Sterile and Non-Sterile Medical Use Alcohol Pad, Sterile and Non-Sterile Undercast Padding, Sterile and Non-Sterile Super Absorbent Dressing, Sterile and Non-Sterile Activated Charcoal Super Absorbent Dressing, Sterile and Non-Sterile Silicone Super Absorbent Dressing, Sterile and Non-Sterile CMC Gelling Fiber Dressing, Sterile and Non-Sterile Hydrogel, Sterile and Non-Sterile Hydrogel Impregnated Gauze Dressing, Sterile and Non-Sterile Skin Protective Barrier, Sterile and Non-Sterile Adhesive Remover Pad, Sterile and Non-Sterile Hydrogel Burn Bandage, Sterile and Non-Sterile Hydrogel Sheet Dressing, Sterile and Non-Sterile Non Adhesive Dressing

Cotton Products, including: Sterile and Non-Sterile Medical Use Cotton Roll, Sterile and Non-Sterile Medical Use Cotton Ball, Sterile and Non-Sterile Medical Use Cotton Swab, Sterile and Non-Sterile Dental Cotton, Sterile and Non-Sterile ABD Pad, Sterile and Non-Sterile Gauze combine Cotton pad, Sterile and Non-Sterile Gauze combine Cotton ball, Sterile and Non-Sterile Nursing Pad



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**Facility(ies):**

Winner Medical (Chongyang) Co., Ltd.  
Te 1, Winner Avenue, Qingshan Industrial Zone, Qingshan Town,  
437542 Chongyang, Hubei, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Bandages and Tapes, including:  
Non-Sterile Gauze Bandages



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## Facility(ies):

Winner Medical (Huanggang) Co., Ltd.  
Winner Industrial Park, Te 1, Chibi Road, 438000 Huanggang,  
Hubei, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of below products :

Synthetic Non-Woven Products, including: Sterile and Non-Sterile Medical Use Face Masks, Sterile and Non-Sterile Medical Use Caps

Bandages and Tapes, including: Non-Sterile Elastic Bandages, Non-Sterile Elastic Adhesive Bandages, Non-Sterile Plaster of Paris Bandages, Non-Sterile Soft Silicone Tapes, Sterile and Non-Sterile Silicone Plaster

Special Dressing Products, including: Sterile and Non-Sterile Hydrocolloid Plaster, Sterile and Non-Sterile Plaster, Sterile and Non-Sterile Medical Tapes, Non-Sterile Finger Bandage, Sterile and Non-Sterile Medical Use PE Gloves, Sterile and Non-Sterile Non-woven Wound Dressing, Sterile and Non-Sterile Transparent wound Dressing, Sterile and Non-Sterile Non Adhesive Dressing, Sterile and Non-Sterile Alginate Dressing, Sterile and Non-Sterile Foam Dressing, Sterile and Non-Sterile Hydrocolloid Dressing, Sterile and Non-Sterile Silicone Foam Dressing, Sterile and Non-Sterile Silicone Wound Contact Layer, Sterile and Non-Sterile Silicone Scar Repair Sheet, Sterile and Non-Sterile Silicone Scar Gel



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## Facility(ies):

Winner Medical (Chongyang) Co., Ltd.  
No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang,  
Hubei, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of below products :

Gauze Products, including: Sterile and Non-Sterile Swabs/Sponges without X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges without X-ray Detectable Element, Sterile and Non-Sterile Balls without X-ray Detectable Element, Sterile and Non-Sterile Swabs/Sponges with X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges with X-ray Detectable Element, Sterile and Non-Sterile Balls with X-ray Detectable Element, Sterile and Non-Sterile O.R. Towels

Cotton Non-Woven Products, including: Sterile and Non-Sterile Balls without X-ray Detectable Element, Sterile and Non-Sterile Balls with X-ray Detectable Element, Sterile and Non-Sterile O.R. Towels, Sterile and Non-Sterile Cotton Spunlace Non-Woven Surgical Gown

Synthetic Non-Woven Products, including: Sterile and Non-Sterile Surgical Gowns, Sterile and Non-Sterile Medical Use Protective Clothes, Sterile and Non-Sterile Medical Use Isolation Gown, Sterile and Non-Sterile Medical Use Shoe Covers





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## Facility(ies):

Winner Medical (Chongyang) Co., Ltd.  
No. 9A, Jincheng Avenue, Zhongjin Village, Tiancheng Town,  
437500 Chongyang, Hubei, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of below products :

Gauze Products, including: Sterile and Non-Sterile Swabs/Sponges without X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges without X-ray Detectable Element, Sterile and Non-Sterile Balls without X-ray Detectable Element, Sterile and Non-Sterile Rolls without X-ray Detectable Element, Sterile and Non-Sterile Swabs/Sponges with X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges with X-ray Detectable Element, Sterile and Non-Sterile Balls with X-ray Detectable Element, Sterile and Non-Sterile Rolls with X-ray Detectable Element, Sterile and Non-Sterile Trach Sponges

Cotton Non-Woven Products, including: Sterile and Non-Sterile Swabs/Sponges without X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges without X-ray Detectable Element, Sterile and Non-Sterile Rolls without X-ray Detectable Element, Sterile and Non-Sterile Swabs/Sponges with X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges with X-ray Detectable Element, Sterile and Non-Sterile Rolls with X-ray Detectable Element, Sterile and Non-Sterile Trach Sponges

Synthetic Non-Woven Products, including: Sterile and Non-Sterile Swabs/Sponges without X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges without X-ray Detectable Element, Sterile and Non-Sterile Balls without X-ray Detectable Element, Sterile and Non-Sterile Rolls without X-ray Detectable Element, Sterile and Non-Sterile Swabs/Sponges with X-ray Detectable Element, Sterile and Non-Sterile Lap Sponges with X-ray Detectable Element, Sterile and Non-Sterile Balls with X-ray Detectable Element, Sterile and Non-Sterile Rolls with X-ray Detectable Element, Sterile and Non-Sterile Medical Use Bed Hygienic Sheets, Sterile and Non-Sterile Medical Use Hygienic Pillow Covers, Sterile and Non-Sterile Medical Use Sleeve Covers, Sterile and Non-Sterile Medical Use Aprons, Sterile and Non-Sterile Surgical Drapes, Sterile and Non-Sterile Non-Surgical Drapes

Special Dressing Products, including: Sterile and Non-Sterile Medical Use Applicators, Non-Sterile Sterilization Pouches, Sterile and Non-Sterile Medical Use Bibs, Sterile and Non-Sterile Tongue Depressors, Sterile and Non-Sterile Medical Use Paper Towel, Sterile and Non-Sterile Medical Use PE Sleeve Covers, Sterile and Non-Sterile Medical Use PE Aprons, Sterile and Non-Sterile Medical Use PE Shoe Covers, Sterile and Non-Sterile Undercast Padding, Sterile and Non-Sterile Non-woven Wound Dressing, Sterile and Non-Sterile Transparent wound Dressing, Sterile and Non-Sterile Super Absorbent Dressing, Sterile and Non-Sterile NPWT Gauze Dressing Kit, Sterile and Non-Sterile NPWT Foam Dressing Kit

Cotton Products, including: Sterile and Non-Sterile Medical Use



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Eye pad, Sterile and Non-Sterile ABD Pad, Sterile and Non-Sterile Gauze combine Cotton pad, Sterile and Non-Sterile Gauze combine Cotton ball, Sterile and Non-Sterile Nursing Pad

Sterile and Non-Sterile Basic Dressing Packs



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## Facility(ies):

Winner Medical Co., Ltd., Shenzhen Branch  
101-401, Building A, Markwins Industrial Park, No. 3 Technology  
Road, Zhukeng Community, Longtian Sub-district, 518109  
Pingshan District, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of below products :

Synthetic Non-Woven Products, including: Sterile and Non-Sterile  
Medical Use Face Masks, Sterile and Non-Sterile Surgical Gowns,  
Sterile and Non-Sterile Medical Use Protective Clothes, Sterile and  
Non-Sterile Medical Use Isolation Gown, Sterile and Non-Sterile  
Medical Use Bed Hygienic Sheets, Sterile and Non-Sterile Medical  
Use Hygienic Pillow Covers, Sterile and Non-Sterile Medical Use  
Sleeve Covers, Sterile and Non-Sterile Surgical Drapes, Sterile  
and Non-Sterile Non-Surgical Drapes

Sterile and Non-Sterile Basic Dressing Packs

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