DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 046241 0068 Rev. 02

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Gauze Products, 100% Cotton Non-woven Products, Synthetic Non-woven Products, Bandages and Tapes, Special Dressing Products, Cotton Products, Disposable Medical Devices for Infusion and Transfusion, Surgical Instruments (for detail information see following pages)**

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). See also notes overleaf.

Report No.:	SH1904324
Valid from:	2020-06-01
Valid until:	2023-05-31

Date, 2020-04-23

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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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

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, including:**

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

- **100% cotton non-woven products, including:**

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

- **Synthetic non-woven products, including:**

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

- **Bandages and Tapes, including:**

  Triangular Bandages, Gauze Bandages (washed and unwashed), Elastic Bandages, Elastic Adhesive Bandages, Plaster of Paris Bandages, Soft Silicone Tapes, Silicone Band Aid

- **Special Dressing Products, including:**

  Adhesive Plasters, First Aids, Finger Bandage, Applicators, Sterile Pouches, Bibs, Tongue Depressors, Identity Bands, Adhesive Taps, Paper Towel, Paper Mask, PE Products (Sleeves, Aprons, Gloves, Shoe Covers), Alcohol Pad, Cast Padding, Wound Dressing, Alginate Dressing, Foam Dressing, Hydrocolloid Dressing, Super Absorbent Dressing, Silicone Foam Dressing, Silicone Contact Layer, Activated Charcoal Super Absorbent Dressing, NPWT Gauze Dressing Kit and NPWT Foam Dressing Kit, Silicone Super Absorbent Dressing

- **Cotton Products, including:**

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

- **Disposable Medical Devices for Infusion and Transfusion, including:**

  Disposable Syringe Sets, Drainage Bags

- **Surgical Instruments, including:**

  Basic Dressing Packs, Umbilical Cord Clamps

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