



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

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 046241 0065 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): Sterile and non-sterile Gauze Products,
Sterile and non-sterile Synthetic Non-woven Products
with X-ray detectable element,
Sterile and non-sterile 100% Cotton non-woven
Products with X-ray detectable element,
Basic Dressing Packs with Class IIa/IIb elements,
Alginate Dressing, Foam Dressing,
Hydrocolloid Dressing, Silicone Foam Dressing,
Silicone Contact Layer, Super Absorbent Dressing,
Activated Charcoal Super Absorbent Dressing,
Silicone Super Absorbent Dressing,
NPWT Gauze Dressing Kit,
NPWT Foam Dressing Kit
(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 design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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



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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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[Detailed information on the Product Category(ies)]

Sterile and non-sterile Gauze Products:

Sterile and non-sterile Swab/Sponges(plain and fluff) with X-ray detectable element, Sterile and non-sterile Lap Sponges (washed, unwashed and fluff) 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 Swabs/Sponges without X-ray detectable element, Sterile and non-sterile Lap Sponges without X-ray detectable element

In Facility:

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

Winner Medical (Jingmen) Co., Ltd.

Special No.1 Hangkong Avenue, Pailou, 448121, Jingmen, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

Te 1, Winner Avenue, Qingshan Industrial Zone, Qingshan Town, 437542 Chongyang, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

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

Sterile and non-sterile 100% Cotton non-woven Products:

Sterile and non-sterile Swab/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

In Facility:

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

Winner Medical (Jingmen) Co., Ltd.

Special No.1 Hangkong Avenue, Pailou, 448121, Jingmen, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang, Hubei, P. R. China

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Winner Medical (Huanggang) Co., Ltd.

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

Winner Medical (Chongyang) Co., Ltd.

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

Sterile and non-sterile Synthetic Non-woven Products:

Sterile and non-sterile Swab/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

In Facility:

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

Winner Medical (Jingmen) Co., Ltd.

Special No.1 Hangkong Avenue, Pailou, 448121, Jingmen, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

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

Super Absorbent Dressing, Activated Charcoal Super Absorbent Dressing, Silicone Super Absorbent Dressing

In Facility:

Winner Medical (Jiayu) Co., Ltd.

No. 172 Fenghuang Avenue, 437200 Jiayu, Hubei, P. R. China

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

Alginate Dressing, Foam Dressing, Silicone Foam Dressing, Silicone Contact Layer, Hydrocolloid Dressing

In Facility:

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Winner Medical (Huanggang) Co., Ltd.

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

Basic Dressing Packs with Class IIa/IIb elements

In Facility:

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

Winner Medical (Jingmen) Co., Ltd.

Special No.1 Hangkong Avenue, Pailou, 448121, Jingmen, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

Te 1, Winner Avenue, Qingshan Industrial Zone, Qingshan Town, 437542 Chongyang, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

No. 8, Jincheng Avenue, Tiancheng Town, 437500 Chongyang, Hubei, P. R. China

Winner Medical (Chongyang) Co., Ltd.

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

NPWT Gauze Dressing, NPWT Foam Dressing Kit

In Facility:

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, P. R. China

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