



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 059619 0018 Rev. 00**

### Manufacturer

**Haian Medigauze Co., Ltd.**

Jiaoxie Industry park  
226633 Haian, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

### Product Category(ies):

Gauze Sponge without X-ray,  
Gauze Ball without X-ray,  
Non-woven sponge, Non-woven face mask,  
Surgical gown, Isolation gown/ Coverall,  
Disposable underpad, Alcohol pad, Surgical Drape,  
Disposable Examination Gloves,  
Wooden Tongue Depressor

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.: SH1945514  
Valid from: 2019-10-28  
Valid until: 2021-07-06

Date, 2019-10-28

*S. Preis*

Stefan Preis  
Head of Certification Notified Body



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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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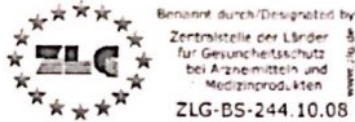
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# EC Certificate

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 059619 0018 Rev. 00**

**Facility(ies):** Haian Medigauze Co., Ltd.  
Jiaoxie Industry park, 226633 Haian, Jiangsu, PEOPLE'S  
REPUBLIC OF CHINA



TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
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# Certificate

No. Q6 059619 0017 Rev. 00

**Holder of Certificate:** Haian Medigauze Co., Ltd.  
Jiaoxie Industry park  
226633 Haian, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Haian Medigauze Co., Ltd.  
Jiaoxie Industry park, 226633 Haian, Jiangsu, PEOPLE'S  
REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** Production and Distribution of  
Lap Sponge, Gauze Sponge with X-ray, Gauze Ball  
with X-ray, Gauze Sponge without X-ray, Gauze  
Ball without X-ray, Absorbent Gauze, Non-woven  
Sponges, Non-woven Face Mask, Surgical Gown,  
Isolation Gown/Coverall, Disposable Underpad,  
Surgical Drape, Disposable Examination Gloves,  
Wooden Tongue Depressor, Alcohol Pad, Elastic  
Bandage, Cotton Roll/Wool, Cotton Ball, Non-  
woven Cap, Non-woven Shoe Cover, Disposable  
Sleeve Cover, Cotton Tips

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1945514  
**Valid from:** 2019-10-31  
**Valid until:** 2021-06-30

**Date,** 2019-10-31

*C. Dicks*  
Christoph Dicks  
Head of Certification, Notified Body

