



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 109397 0004 Rev. 00**

**Manufacturer:**

**Xuchang Zhende Surgical  
Dressing Co., Ltd.**

Area A, Baihua Road East  
South Side of Erji river  
Industry Cluster District  
Yanling County  
461200 Xuchang Henan  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** Lap Sponge,  
Gauze Products with X-ray thread,  
Gauze Products without X-ray thread,  
Non Woven Products with X-ray thread,  
Non Woven Products without X-ray thread  
Procedural Dressing Trays  
(see the details in next page)

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. 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:G1 109397 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G1_109397_0004_Rev_00)

**Report No.:** SH2049502

**Valid from:** 2020-11-10

**Valid until:** 2024-03-03

**Date,** 2020-11-10

Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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 109397 0004 Rev. 00**

**Product(s)/Product Category(ies)**

- **Gauze Products with X-ray thread**  
Gauze Swab, Gauze Sponge, Gauze Roll, Gauze Ball, Zig-zag Gauze,  
Gauze
- **Gauze Products without X-ray thread**  
Gauze Swab, Gauze Sponge, Gauze Roll, Gauze Ball, Zig-zag Gauze,  
Gauze
- **Non-woven Products with X-ray thread**  
Non-woven Swab, Non-woven Sponge, Non-woven Ball
- **Non-woven Products without X-ray thread**  
Non-woven Swab, Non-woven Sponge, Non-woven Ball