



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 109397 0005 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**

**Sterile Gauze Swab without X-ray Thread,**

**Category(ies):**

**Sterile Non-woven Swab**

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. 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:G2S 109397 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G2S_109397_0005_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 ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT