



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 080946 0010 Rev. 02**

## Manufacturer

**Anji SPENQ Industrial Co., Ltd.**

F16, Building C  
Anji Chamber of Commerce Mansion  
No. 99 Tianhuangping South Road  
313300 Anji County, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

## Facility(ies):

Anji SPENQ Industrial Co., Ltd.  
F16, Building C, Anji Chamber of Commerce Mansion, No. 99  
Tianhuangping South Road, 313300 Anji County, Zhejiang  
Province, PEOPLE'S REPUBLIC OF CHINA

## Product

### Category(ies):

**Disposable Vaginal Speculums, Disposable Colostomy  
Bags, Disposable Vaginal Irrigation Sets, Urine Bags,  
Umbilical Cord Clamps, Sterile Latex Examination  
Gloves, Wound Plasters, Liquid Transfusion Plasters,  
Adhesive Wound Dressings, First-Aid Kits, Sterile  
Gauze Sponges, Rectal Tubes, Skin Closure Strips,  
Surgical Drapes, Sterile Surgical Gown, Absorbent  
Cotton Rolls, Absorbent Cotton Balls, Absorbent  
Cotton Pads, Eye Pad, Abdominal Pads, Non-woven  
Swabs, Lap Sponge, Gauze Roll**

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.:** SH1960110

**Valid from:** 2019-11-13

**Valid until:** 2020-11-23

**Date,** 2019-11-13

Christoph Dicks  
Head of Certification/Notified Body

TÜV SÜD  
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT

A4 / 07.17