



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. 03**

## 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.:** SH19601EXT01

**Valid from:** 2020-01-29

**Valid until:** 2024-05-26

**Date,** 2020-01-29

Christoph Dicks  
 Head of Certification/Notified Body