



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 16 08 80946 010

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

Tangpu Economic Development Zone  
313300 Anji City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** SUNGO Certification Company Limited

RM101, MAPLE HOUSE  
118 HIGH STREET, PURLEY  
LONDON  
CR8 2AD  
UNITED KINGDOM



**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, Paediatric Urine Collector, Sterile Non-adherent Pads, 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.:** SH1660107

**Valid from:** 2016-12-20

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



**Date,** 2016-12-20

Stefan Preiß

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

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Facility(ies):

Anji SPENQ Industrial Co., Ltd.  
Tangpu Economic Development Zone, 313300 Anji  
City, Zhejiang Province, PEOPLE'S REPUBLIC OF  
CHINA

ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT