

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.:

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Valid from:

2019-11-13

Valid until:

2020-11-23

Date, _____

2019-11-13

C.D.H

Christoph Dicks

Head of Certification/Notified Body