

Declaration of Conformity

Manufacturer:

Name: Anji SPENQ Industrial Co., Ltd.

Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:

Name: SUNGO Europe B. V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:

F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: 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, Lab Sponges, Gauze Roll

Classification of products: I STERILE

CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

We hereby declare:

The above-mentioned CE-marked products comply with medical device directives and standards, and meet the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

Directive

Applicable directives: Medical Device Directives – MDD 93/42/EEC (14.06.1993).

Standards: All applicable EU-harmonized standards.

Certification body: TUV SUD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123

EC Certification No.: G2S 080946 0010 Rev. 03

Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:

Location: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Declaration person: Li Wenhui

Position: General Manager 安吉鑫洋进出口有限公司

Place: Anji City, China ANJI SPENQ INDUSTRIAL CO., LTD

Signature of issue person:

Date: February 25, 2021

