# 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**: <u>I STERILE</u>

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. 02 Expiry date of CE Certificate: 2020-11-23

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 Wenhu Position: General Manager Place: Anji City, China Signature of issue person: Date: November 24, 2019

