

安吉鑫沅进出口有限公司

ANJI SPENQ INDUSTRIAL CO., LTD.

地址: 浙江省安吉塘浦经济开发区 电话: +86 572 5882801 传真: +86 572 5676519

ADD: Tangpu Development Zone, Anji, Zhejiang, China Tel: +86 572 5882801 Fax: +86 572 5676519

Declaration of Conformity

Manufacturer:

Name: Anji SPENQ Industrial Co., Ltd.

Address: Tangpu Economic Development Zone, 313300 Anji City, Zhejiang Province, People's Republic of China.

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

EC-Representative:

Name: SUNGO Certification Company Ltd.

Address: RM 101, Maple House, 118 High Street, Purley, London, CR8 2AD, United Kingdom.

Manufacturing Sites:

Tangpu Economic Development Zone, 313300 Anji City, Zhejiang Province, People's Republic of China.

Product Names: Paediatric Urine Collector, Vaginal Speculum, Colostomy Bag, Umbilical Cord Clamps, Rectal Tubes, Sterile Latex Examination Gloves, Wound Plaster, I.V. Plaster (Liquid Transfusion Plaster), Adhesive Wound Dressing, Sterile Non-adherent Pad, Sterile Surgical Gown, Eye Pad, Abdominal Pad, Sterile Cotton Ball, Sterile Gauze Sponge, Skin Closure Strips, First-Aid Kit, Lap Sponge, Surgical Drape, Urine Bag, Sterile 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.

Directives

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

Standards: All applicable EU-harmonized standards.

Certification body: TÜV SÜD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123

EC Certification No.: G2S 16 08 80946 010

Expiry date of CE Certificate: 23.11.2020

The distribution date of first CE-marked products:

Location: Tangpu Economic Development Zone, 313300 Anji City, Zhejiang Province, People's Republic of China.

Declaration person: Li Wenhua 安吉鑫沅进出口有限公司

Position: General Manager ANJI SPENQ INDUSTRIAL CO., LTD

Place: Anji City, China

Signature of issue person:

Date: May 01, 2017