

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: Latex Foley Catheters, Oxygen Masks, Sterile Blood Lancets, Sterile Latex Surgical Gloves, Digital Thermometers, Blood Pressure Monitors, Sterile Syringes for Single Use, Sterile infusion Sets for Single Use, Sterile intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Blood Transfusion Sets for Single Use, Nasal Oxygen Cannulas, Suction Catheters, Stomach Tubes, Feeding Tubes, Nelaton Catheter, Disposable Surgical Blades, Endotracheal Tubes, Laryngeal Mask, Reinforced Endotracheal Tube, Mucus Extractor, Tracheostomy Tube, Silicone Foley Catheter.

Classification of products: IIa, IIb or III

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 0007 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 Wenhui

Position: General Manager

Place: Anji City, China

Signature of issue person:

Date: November 24, 2019