

安吉鑫洋进出口有限公司

ANJI SPENQ INDUSTRIAL CO., LTD.

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Declaration of Conformity

Manufacturer:

Name: Anji SPENQ Industrial Co., Ltd.

Address: F16, Bulding 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, Bulding 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 Cannulaes, 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.

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.: G2 080946 0007 Rev. 01

Expiry date of CE Certificate: 23.11.2020

The distribution date of first CE-marked products:

Location: F16, Bulding 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: December 3, 2018

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