# Declaration of Conformity

## Manufacturer:

Name: Shaoxing Gangfeng Hospital Products Co., Ltd. Address: Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China Tel: 0086-575-88086566 Fax: 0086-575-88081711

## **EC-Representative:**

Name: SUNGO Europe B. V. Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

## Manufacturing Sites:

Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China

**Product Names**: Gauze Swabs (Sponges), Gauze Balls, Sterile Gauze Bandages and Sterile Non-woven Would Care Products, Gauze in Roll, Gauze in Zigzag, Cutted Gauze, Medical Elastic Bandage, First Aid Kits, Absorbent Cotton, Cotton Tip Applicator

## 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 038500 0026 Rev. 00

Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products: Location: Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China

Declaration person: Michelle Tao

Position: Director Place: Gaobu City, China Signature of issue Plasoing Gangfeng Hospital Products Co.,Ltd. Date: November 11, 2019 正纪茶