

# 绍兴港峰医用品有限公司

**SHAOXING GANGFENG HOSPITAL PRODUCTS CO., LTD.**

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## 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 name:** Gauze Bandage (5m x 5cm, 5m x 6cm, 5m x 7cm, 5m x 10cm, 7m x 5cm, 7m x 6cm, 7m x 7cm, 7m x 10cm, 7m x 14cm)

**Classification of product:** I Non-sterile

CE Conformity Assessment Route: Self Declaration

### We hereby declare:

The above-mentioned CE-marked product is in compliance with medical device directives and standards, and meets the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

## Directives and Standards

Applicable directives: Medical Device Directives – MDD 93/42/EEC (1993-06-14).

Standards: All applicable EU-harmonized standards + EN 14079:2003

Certification body: The quality management system of our company is certificated by TUV Product Service Ltd. Certificate number Q6 18 04 38500 023 until 2021.06.30

The distribution of the first CE-marking products:

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

Declaration person: Michelle Tao

Position: General Manager

Place: Gaobu City, China

Date: September 8, 2020

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王纪荣