

Declaration of Conformity

Manufacturer:

Name: Taizhou Kangping Medical Science And Technology Co., Ltd.

Address: Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China

Tel: 0086-523-86299168 Fax: 0086-523-86277168

EC-Representative:

Name: MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munchen, Germany

Manufacturing Sites:

Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China

Product Name: Alcohol Prep Pad

Model: (LA-015)

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 088678 0004 Rev. 02

Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:

Location: Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China

Declaration person: Mr. Evan Gao

Position: General Manager

Place: Taizhou, China

Signature of issue person:

Date: December 16, 2021

陈阿平

泰州市康平医疗科技有限公司

Taizhou KangPing Medical Science And Technology Co.,Ltd