

Declaration of Conformity

Manufacturer:

Name: Changzhou Chuangjia Medical Appliance Co. Ltd.

Address: Sanhekou Development Zone, Zhenglu Town, 213115 Changzhou, China

EC-Representative:

Name: SUNGO Europe B. V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:

Sanhekou Development Zone, Zhenglu Town, 213115 Changzhou, China

Product Names: Sterile Vaginal Speculum, Sterile Vaginal Irrigator, Sterile Medical Mouthpiece, Sterile Urine Drainage Bag, Sterile Medical Sampler, Sterile Gynecological Examination Set (incl. Cervical Brush/Broom), Disposable Irrigation Syringe (Feeding Syringe)

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 076830 0011 Rev. 02

Date of issue: 2021-03-19

The distribution of first CE-marked products:

Location: Sanhekou Development Zone, Zhenglu Town, 213115 Changzhou, China

Declaration person: Xu Jia

Position: General Manager

Place: Zhenglu, China

Signature of issue person:

Date: March 19, 2021 **Changzhou Chuangjia Medical Appliance Co.,Ltd**

常州创佳医疗器械有限公司

徐佳