

常州市创佳医疗器械有限公司

Changzhou Chuangjia Medical Appliance Co., Ltd.

Declaration of Conformity

Manufacturer:

Name: Changzhou Chuangjia Medical Appliance Co., Ltd.

Address: Sanhekou Development Zone, Zhenglu Town 213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

EC-representative:

Name: Lotus Global Co., Ltd

Address: 1 Four Seasons Terrace, West Drayton
Middlesex, London UB7 9GG UNITED KINGDOM

Product name:

Sterile Vaginal Speculum,

Sterile Vaginal Irrigator,

Sterile Medical Mouthpiece,

Sterile Urine Drainage Bag,

Sterile Meical Sample,

Sterile Gynecological Examination Set (Cytobrush, Cervical Spoon, Sterile Latex Gloves)

Classification of product: I-Sterile

CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

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

Applicable directives: Medical Device Directives - MDD93/42/EEC (1993-06-14).

Standards: All applicable EU-harmonized standards

Certification body: The quality management system of our company is certificated by TUV SUD Product Service

Identification Number: CE0123

EC Certificate No.: G2S 17 11 76830 011

Expiry date of CE Certificate: 2022-01-09

The distribution date of first CE-marking products:

Location: Sanhekou Development Zone, Zhenglu Town, 213115 Changzhou, PEOPLE'S
REPUBLIC OF CHINA

Declaration person: Xu Jia

Position: General Manager

March 12, 2018

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徐佳