

## SF/CE-02-01 DECLARATION OF CONFORMITY

**Manufacturer:** Changzhou Shunfeng Plastic Co., Ltd.

Shunbei Country Zhenglu Town Tianning Area, 213116, Changzhou City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

TEL: +86-519-88902385

FAX: +86-519-88909276

**European Representative:** Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

TEL: 0049-40-2513175

FAX: 0049-40-255726

**Product Name:** Sterile Cervical Brush for Single Use

**UMDNS Code:** 10500

**Classification (MDD, Annex IX):** I-sterile, Rule 5

**Conformity Assessment Route:** Annex V.3

We herewith declare that the above mentioned products meet the transportation into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are under the premises of the manufacture.

### DIRECTIVE

**General applicable directives:**

**Medical Device Directive:** COUNCIL DIRECTIVE 93/42/EEC of THE EUROPEAN AND OF THE COUNCIL (Council Directive 93/42/EEC)


**Standard Applied:** See (harmonized-EN) standards list in the technical file which documented evidence of compliance can be provided.

**Notified Body:** TÜV SUD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

**Identification number:** 0123

(EC) Certificate(s): G2S 072517 0009 REV.01

Expire date of the Certificate: 2024-05-26

Signature: 

Name: Qing Xu

Position: General Manager

Place, Date: Changzhou, China; 2019.08.28

