# *EC Declaration of Conformity*

*Manufacturer:*

**Taizhou Kangjian Medical Equipment Co., Ltd.**

**The machine electricity zone (Hang Ni Kan)of**

**Yuhuan county, Zhejiang province317600, P. R. China**

*whose single Authorized Representative:*

**MedPath GmbH**

**Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany**

We, the manufacturer, herewith declare that the products

**Sterile Vaginal Speculum for Single Use**

**Modle: L (large), M (middle), S (small), XS (extra small), XXS(extra XS)**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex Annex V of Directive 93/42/EEC and MDD 2007/47/EEC modification included.

Compliance of the designated product with the Directive 93/42/EEC (MDD 2007/47/EEC modification included) has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**

**Tillystraße 2, 90431, Nürnberg, Germany**

**Certificate No.: DD601478060001**

**Issue date: 2020-09-03**

**Expiry date:2024-05-26**

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC(MDD 2007/47/EEC modification included).

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Digitally signed by Chicu Natalia
Date: 2023.09.29 16:19:32 EEST
Reason: MoldSign Signature
Location: Moldova

**Company: Taizhou Kangjian Medical Equipment Co., Ltd.**

**Address: The machine electricity zone (Huang Ni Kan) of**

**Yuhuan county, Zhejiang province317600, P. R. China**

*Yuhuan/2020-09-04*

*Place, date*

*,general manager*

*Legally binding signature, Function*

台州康健医用器械有限公司
TAIZHOU KANGJIAN MEDICAL EQUIPMENTS CO.,LTD.