

# Changzhou Huankang Medical Device Co., Ltd.

Add: 22 Changhe Road, Sanhekou, Zhenglu 213116 Changzhou, Jiangsu P.R. China

Tel: 0086-519-88909800 Fax: 0086-519-88906900

Email: hk@huankang.com

## EC Declaration of Conformity

*Manufacturer:*

Changzhou Huankang Medical Device Co., Ltd.  
ADD: 22 Changhe Road, Sanhekou, Zhenglu  
213116 Changzhou, Jiangsu P.R. China

*whose single Authorized Representative:*

SUNGO Europe B.V.  
ADD: Olympisch Stadion 24,  
1076DE Amsterdam, Netherlands

We, the manufacturer, herewith declare that the products

### DISPOSABLE GYNECOLOGICAL KITS

UMDNS-Code: **[13-887]**

meet the provisions of Directive 93/42/EEC amended by 2007/47/EC which apply to them.

The medical device has been assigned to **class Ila** according to Annex IX of the Directive 93/42/EEC amended by 2007/47/EC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC amended by 2007/47/EC.

Compliance of the designated product with the Directive 93/42/EEC amended by 2007/47/EC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: DD 601497740001

Issue date: 2020-08-28

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 amended by 2007/47/EC.

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

**Changzhou Huankang Medical Device Co., Ltd.**

**ADD: 22 Changhe Road, Sanhekou, Zhenglu 213116 Changzhou, Jiangsu P.R. China**

SEP. 15, 2020, Changzhou

*Place, date*

ZHAI CAILONG, CEO

*Legally binding signature, Function*

常州市环康医疗器械有限公司  
CHANGZHOU HUANKANG MEDICAL DEVICE Co.,LTD