

Changzhou Huankang Medical Device Co., Ltd.

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

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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 VAGINAL SPECULUMS

UMDNS-Code: [11-267]

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 Is 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

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

Legally binding signature, Function