文件名称: 符合性声明

生效日期: 2020.08.01

文件编号: HN/CE-002-20

## **EC Declaration of Conformity**

Manufachuner:

Huaian Hening Medical Instruments Co.,Ltd. NO.6,West Hongdou Road,Economic Development Zone,Huaian, Jiangsu,22305 China

Authorized Representative:

Shanghai International Hoding Corp.GmbH(Europe)

Eiffestrasse 80,20537 Hamburg, Germany Tel:0049-40-2513175 Fax:0049-40-255726

Vat No : DE166892350

We, the manufacturer, here with declare that the products

Alcohol pad

SIZE: 30\*60, 65 x 35 mm (±5 mm) and 60 x 60 mm (±5 mm)

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

The medical device has been assigned to class la according to Annex V 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 V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TUV Rheinland LGA Products GmbH Tillystra β e 2,90431,Nürmberg,Germany Certificate No.:DD 60082383 0001

> Issue date:2018-03-19 Expiry date:2023-02-19

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Huaian Hening Medical Instruments Co., Ind.

NO.6, West Hongdou Road, Economic Development Zone, Huaian France L.

China Huaian 2021-04-12

Place, date

GME Dazhengcan

Legally binding signature unct