KANGJI

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Hangzhou Kangji Medical Instrument Co.,Ltd No.1668 Chunjiang East Road,Economic Development Zone Tonglu, Hangzhou, Zhejiang ,311501,China SRN: CN-MF-000008708

Llins Service & Consulting GmbH Heinigstrasse 26, 67059 Ludwigshafen, Germany SRN: DE-AR-000009077

We, the manufacturer, herewith declare that the products

Disposable Veress needles

GMDN-Code/Preferred Terms: <u>12750</u> detailed refs see the attachment 1

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

The medical device has been assigned to class II a according to Annex IX rule 7 of the Directive 93/42/EEC. The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC. Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body:

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

Certificate No.: HD 60147407 0001 Issue date: 2020-03-05 Expiry date: 2024-05-26

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

Company: Hangzhou Kangji Medical Instrument Co., Ltd **Address:** No.1668 Chunjiang East Road, Economic Development Zone Tonglu,

Hangzhou, Zhejiang ,311501,China



Hangzhou, 2024-05-31 Place, date

 attachment 1-list of additional references applicable to the Declaration of Conformity

 Product
 KJ Code

 MHC code

 Disposable
 105Y.202

 800105

 veress needle
 105Y.205