

Declaration of conformity

Manufacturer: Jiangsu Kangjin Medical Instrument Co., Ltd.

Zhenglu Town

213111 Changzhou

PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80 20537 Hamburg GERMANY

Product Name: Enteral Feeding Set for Single Use(Gravity Feed)

Model Number: EN-02, EN-04

UMDNS CODE: 11677

Classification (MDD, Annex IX): I Sterile, Rule 2

Conformity Assessment Route: MDD Annex II excluding (4)

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and all applicable harmonized Standards. All supporting documentations are retained under the premises of the manufacturer.

Jiangsu Kangjin Medical Instrument Co., Ltd is exclusively responsible for DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339 München, Germany NB

NB Identification NO.: 0123

(EC)Certificate(s): G2S 039452 0032 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: Dec, 2013

Place, Date of Issue: Kangjin, 2021.01.06

Signature: JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.

Name:

Position:  President