

Declaration of Conformity

1. Company name and address:

Company name: Jiangsu Kangjin Medical Instrument Co.,Ltd Company address: Zhenglu Town 213111, Changzhou, P.R.C.

2. Product name: Endoscopic injection needle for single use

GMDN CODE: 17569

Classification (MDD, Annex IX): II a , Rule 6

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

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

3. Authentication institution:

Certification Notify Body:

TÜVSÜD Product Service GmbH ·Zertifizierstelle·Ridlerstrasse 65 · 80339 München· Germany NB identification no.: 0123

4, CE Certificate No.

Certificate No.: G1 039452 0033 Rev. 01

Valid until: 2024-05-26

5. President signature:

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.

W WE 72 President

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.