Declaration of Conformity

Manufacturer: Ningbo Foyomed Medical Instruments Co., Ltd.

Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone, 315040, Ningbo, PEOPLE'S REPUBLIC OF CHINA

European Representative: Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf (Germany)

Product Name: Disposable Syringes UMDNS Code: 13929 Produce No.: FY0601, FY0604

Classification (MDD, Annex IX): IIa, rule 6.

Conformity Assessment Route: Annex V

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. We are exclusively responsible for the Declaration of Conformity.

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

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

NB Identification number: 0123

(EC) Certificate(s): G2 093011 0006 Rev.01

Expire date of the Certificate: 2024-05-26 NINGBO FOYOMED MEDICAL INSTRUMENTS CO., LTD

Place, Date of Issue: Ningbo, 2022-03-10

Signature: 2 7 Ref. 123

Name: Yingxia Xu

Position: General Manager