

Declaration of Conformity

Manufacturer: Conod Medical Co., Limited

Address: No.11 Hongfeng Road, Baimao Industrial Park, Changshu City, Jiangsu Province, 215532. P.R. China

European: Shanghai International Holding Corp. GmbH (Europe)

Representative: Eiffestrasse 80, 20537 Hamburg Germany

Product: Pre-filled Syringe with Lubricant Jelly

Product Code: LS6G, LS12G

UMDNS Code: 12-401

Classification (MDD, Annex IX): IIa, Annex IX Rule V

Conformity Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet 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).

Notified Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munchen, Germany

NB Identification Number: 0123

Certificate Number: G2 071789 0045 Rev.00

Expiry Date: 2022-01-15

Start of CE Marking: Not until now

Place, Date: Conod Medical Co., Limited, No.11 Hongfeng Road, Baimao Industrial Park, Changshu City, Jiangsu Province, 215532. P.R. China 2019-06-03

Signature _____



Name: Joey ZHAO

Position: Management Representative
