

Declaration of Conformity

Manufacturer Conod Medical Co., Limited
Address No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu province, PEOPLE'S REPUBLIC OF CHINA

European Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Product Pre-filled Syringe with Lubricant Jell
Model code 5g,6g,8g
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).

Standard:

Harmonized standards published in the official journal of the European communities applicable to this product.

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

NB Identification number: 0123

Certificate: G2 071789 0045 Rev.01

Expiry date of the certificate: 2024-05-26

Start of CE Marking: Not until now

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532, Changshu City, Jiangsu Province. PEOPLE'S REPUBLIC OF CHINA 2019-10-31

Signature

Name: Song pinran

Position: Management Representative

江苏康诺医疗器械股份有限公司
CONOD MEDICAL CO., LIMITED