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
SRN: CN-MF-000012600

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestraße 80, 20537 Hamburg, GERMANY
SRN: DE-AR-000000001

Device Name: Pre-filled syringe
EMDN Code: A02010701, A02010702

Product name	Basic UDI-DI	Remark
Pre-filled syringe	69558240CS0200100PS00012E	w/ sterile water,10cc/ml, 20cc/ml, 30cc/ml
Pre-filled syringe	69558240CS0200100PS00022G	w/ glycerine solution, 10cc/ml

Intended Use: Pre-filled syringe is intended to inflate an indwelling urethral Foley catheter balloon.

Classification (MDR, Rule 1 of Annex VIII): Class I in sterile condition
Conformity Assessment Procedure: Annex IX of Regulation(EU) MDR 2017/745

We herewith declare that the bellow mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Device and applicable harmonized standards. All supporting documentations are retained under the premises of the manufacturer.

Regulation

General applicable regulations:

Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Notified Body: TÜV SÜD Product Service GmbH
Address: Ridlerstraße 65, 80339 Munich, Germany
NB Identification number: 0123
Certificate: G11 071789 0050 Rev.01
Expiry date of the certificate: 2027-10-16

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

2024-12-24

Signature Yangcheng

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

Name：Yang, Chong
Position: Deputy Director of Quality and Regulatory Affairs