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

Product Name: Urethral Catheter
EMDN Code: U010299 Urethral Prostatic and Bladder Catheters, with Balloon-Other

Basic UDI-DI:
Two-way:69558240CS0400100US00016R
Three-way: 69558240CS0400100US00026T

Model and size:
Two-way： Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22, Fr24, Fr26
Three-way： Fr12, Fr14, Fr16, Fr18, Fr20, Fr22, Fr24, Fr26

Classification (MDR, Rule 5 of Annex VIII): IIb
Conformity Assessment Route: Annex IX of Regulation (EU) MDR 2017/745

We herewith declare that the above mentioned products meet the provisions of the following regulation and harmonized standards published on the Official Journal of the European Union, and that this EU declaration of conformity is issued under the sole responsibility of Conod Medical Co., Limited.

Regulations

General applicable regulations

Medical device directive: Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017

Notified Body: TÜV SÜD Product Service GmbH
Address: Ridlerstraße 65, 80339 Munich, Germany
NB Identification Number: 0123
Certificate Number: G10 071789 0049 Rev.01
Expiration 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, P.R. China 2024-09-10

Signature Yang Chong 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